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Supreme Court, U.S.
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IN THE

Supreme Court of the United States

APOTEX CORP.,
Petitioner,

v.

MERCK & CO., INC.,
Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED FOR REVIEW

Whether a district court's grant of summary judgment in an independent action alleging fraud in obtaining a favorable judgment should be reviewed on appeal only for abuse of discretion.

PARTIES TO THE PROCEEDING

The parties to the proceeding are identified in the caption.

Pursuant to this Court's Rule 29.6, petitioner Apotex Corporation states that it is a corporation organized and existing under the laws of the state of Delaware with its principal place of business in Weston, Florida and is a subsidiary of Aposherm, Inc., a corporation organized and existing under the laws of Canada. No publicly traded company owns 10% or more of Apotex's stock.

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IN THE

Supreme Court of the United States

Apotex Corp.,

Petitioner,

v.

Merck & Co., Inc.,

Respondent.

Petitioner Apotex Corp. ("Apotex") respectfully requests that this honorable Court grant the petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS AND ORDERS ENTERED BELOW

The decision of the court of appeals is reported at 507 F.3d 1357 (Fed. Cir. 2007) and is reproduced in the appendix at 1a–12a. The decision of the district court is unreported and is reproduced in the appendix at 13a–32a.

JURISDICTION

The United States Court of Appeals for the Federal Circuit entered its opinion constituting its judgment on November 16, 2007. Pet. App. 1a. The court of appeals denied Apotex's timely petitioned for rehearing or rehearing *en banc* on December 28, 2007. Pet. App. 33a–34a. This Court

has jurisdiction over this petition under 28 U.S.C. § 1254(1).

RULES INVOLVED

Federal Rule of Civil Procedure 60 provides, in pertinent part: "This rule does not limit the power of a court to: (1) entertain an independent action to relieve a party from a judgment, order, or proceeding . . . or (3) set aside a judgment for fraud on the court." FED. R. CIV. PROC. 60(d) . Amendments effective December 1, 2007, made various stylistic changes, including a renumbering of the subparts of Rule 60. *See* Pet. App. 43a (Advisory Committee Note). The version of this rule now in effect is reprinted in the Appendix. Pet. App. 35a–43a. The version of the rule in effect before December 1, 2007, is also reprinted in the Appendix. Pet. App. 44a–45a.

STATEMENT OF THE CASE

In 1996, Apotex filed suit against respondent Merck & Co., Inc. ("Merck") alleging that Merck's process for making tablets of the pharmaceutical compound enalapril, marketed under the brand name VASOTEC®, and used to treat high blood pressure, infringed Apotex's United States patents No. 5,573,780 and No. 5,690,962. Pet. App. 2a. The patents involved the following invention, as set forth in claim 1 of the '780 patent:

> 1. A process of manufacture of a pharmaceutical solid composition comprising enalapril sodium, which process comprises the steps of:

> (i) (a) mixing enalapril maleate with an alkaline sodium compound and at least one other excipient, adding water sufficient to moisten, and mixing to achieve a wet mass, or
>
> (b) mixing enalapril maleate with at least one excipient other than an alkaline sodium compound, adding a solution of alkaline sodium compound in water, sufficient to moisten and mixing to achieve a wet mass;
>
> thereby to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water;
>
> (ii) drying the wet mass, and;
>
> (iii) further processing the dried material into tablets.

Id.

Under the patent laws, an applicant is not entitled to a patent if "before such person's invention thereof, the invention was made in this country by another, who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g). In January 2000, the district court ruled that the Apotex patents were invalid under § 102(g), on the ground that the process had been invented and used by Merck before Apotex made the invention set forth in the Apotex patents. *See Apotex Corp. v. Merck & Co.*, No. 96 C 7375, 2000 WL 97582 (N.D. Ill. Jan. 25, 2000). On Apotex's appeal, the Federal Circuit affirmed. *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031 (Fed. Cir. 2001).

In the first infringement action, Apotex argued, in response to the claim that Merck had invented and practiced the patented process well before Apotex, that Apotex was nevertheless entitled to a patent because Merck had suppressed or concealed the invention and practiced it in secret. Pet. App. 3a. The district court rejected Apotex's argument, finding that well before the date that Apotex stated was its invention date, Merck had widely distributed a list of the ingredients in its tableted product. *Id.* To support this finding, the district court relied on purported admissions from Apotex witnesses that "any chemist who knew the ingredients and knew that the process involved adding water to the mix would automatically know that a reaction of the enalapril malete occurred." *Id.* (quoting *Apotex I*, 2000 WL 97582 at *8). In addition, the district court also relied on evidence that in 1994, Merck's vice president of marketing, Brian McLeod, narrated a videotape describing the Merck process, presented during the trial of a lawsuit in Canada in which Merck and its Canadian subsidiary had sued Apotex's Canadian affiliate for infringing Merck's Canadian patent on the enalapril compound. Pet. App. 3a–4a. The Federal Circuit, as it affirmed the district court's ruling that the Apotex patents were invalid based on prior invention by another, held the narration at the Canadian trial to be a public disclosure of Merck's process. *See* Pet. App. 3a–4a; 254 F.3d at 1040.

Some three years later, Apotex filed a new action against Merck alleging that Merck had obtained a favorable judgment in the earlier infringement action by fraud. Pet. App. 13a. Apotex alleged that Merck had falsely stated, in its re-

sponse to a discovery request, that "the entire process was publicly discussed in open court by Brian McLeod during the Canadian Litigation" and falsely stated that "[t]his process has not been abandoned, suppressed, or concealed." Pet. App. 4a. Apotex also alleged that Merck misrepresented facts in its summary judgment brief submitted to the district court and in its appellate brief submitted to the Federal Circuit, and made false statements, including statements that "[t]he details of the process were the subject of public testimony in a court action in Canada"; Brian McLeod provided a "step by step explanation of Merck's process"; "one could reverse-engineer Merck's process by examining Merck's tablets and by reviewing the ingredient list"; "Merck disagrees that it ever suppressed or concealed the invention"; and Merck's "conduct in the late 1980s and early 1990s belies any intention to keep its process secret." Pet. App. 4a–5a. To support these allegations, Apotex relied on testimony from Merck's key witness in *Apotex I*, Dr. Brenner, in a different case between Warner-Lambert Co. and Teva Pharmaceuticals USA, involving quinapril, a compound related to but different from enalapril. Pet. App. 5a. In that case, Dr. Brenner testified:

- The 'lynch pin' [sic] of Merck's process for making stable enalapril tablets was the conversion of enalapril maleate to enalapril sodium, and the key factor in the stabilization of enalapril tablets was the extent to which this reaction went to completion.

- A number of factors played important roles in the stabilization process, including "the type of

mixing equipment, the duration and temperature of the mixing, the holding time in the mixing equipment after mixing, and the particle size of sodium bicarbonate.

- Merck's Canadian demonstration did not disclose that Merck was converting enalapril maleate to enalapril sodium, the above listed factors, or the need to have a complete or virtually complete reaction.

- The process for making enalapril tablets could not be reverse engineered because it would be difficult to determine that there was enalapril sodium in Merck's VASOTEC® tablets.

- Merck decided to maintain as a trade secret the critical process steps for reacting enalapril maleate and sodium bicarbonate to produce enalapril sodium in the wet granulation rather than seeking patent protection for the process.

- Merck had maintained the critical role of sodium bicarbonate in its process a trade secret until December 1994.

- Merck never disclosed its actual process for making VASOTEC® until May 2004.

Pet. App. 16a–17a (citations omitted).

In the new fraud action, Merck moved for summary judgment. Apotex responded by filing:

- a memorandum opposing entry of summary judgment,

- a response under the local rules to Merck's statement of facts,

- Apotex's own statement under N.D. ILL. CIV. R. 56.1(b)(3)(B) of additional facts that it contended raised genuine issues of material fact,[1] and

- an evidentiary declaration containing the evidence that Apotex contended raised genuine issues of material fact with exhibits A through P attached.

The district court concluded that the evidence on which Apotex relied was insufficient to establish fraud, although the court did not frame its discussion in terms of whether there is a genuine issue of material fact. *See* Pet. App. 19a–30a. On Apotex's appeal, the court of appeals affirmed. After acknowledging that the appeal concerned a decision "granting summary judgment in favor of Merck & Co. in an action by Apotex to set aside a judgment", Pet. App. 1a, the court nevertheless stated that "a district court's decision as to whether relief should be granted under rule 60(b) is committed to the sound discretion of the court," Pet. App. 8a, and under that standard affirmed the judgment of the district court on the ground that "the district court's finding that [Merck's process] was not abandoned, suppressed, or concealed was not shown to be error." Pet. App. 9a.

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[1] The pertinent rule of the district court is set out in the appendix. *See* Pet. App. 46a–47a.

REASONS FOR GRANTING THE PETITION

It has long been settled that a victim of fraud in civil litigation may file an independent action seeking relief from the fraudulently obtained judgment. The Federal Rules of Civil Procedure, while recognizing a motion for relief from judgment on the basis of fraud under Rule 60, expressly preserve the right to file an independent action for relief from judgment on grounds of fraud. There is no reason that such a separate action should not be governed by the same rules for summary judgment that apply in all other civil litigation. After all, the Federal Rules of Civil Procedure ordinarily provide that when there is a genuine issue of material fact, a case should go to trial. Surely that rule should apply to an action for relief from a judgment tainted by fraud — the grave nature of such an allegation is no less worthy of trial than any other type of civil litigation in which the evidence is in conflict. Indeed, nothing in Rule 60 exempts independent actions seeking relief from a judgment obtained by fraud from the rules that ordinarily govern summary judgment litigation.

Nevertheless, a split has developed in the circuits about whether an independent action for fraud should be governed by the ordinary rules for summary judgment, or instead is merely a discretionary remedy, the denial of which is reviewed deferentially on appeal for abuse of discretion under the standard applicable to Rule 60 motions. In this case, the court of appeals aligned itself with the circuits that reject de novo appellate review in independent actions seeking relief from a judgment obtained by fraud, but had this case been brought

in another circuit, it would have been governed by quite different standards. This Court should grant certiorari to resolve the split in the circuits and to provide guidance to the lower courts on a matter that has grave implications for the administration of justice.

1. It is well settled that a party that has been the victim of fraud in civil litigation may bring an independent action for fraud. Indeed, one of the leading cases establishing this proposition involved patent litigation.

In *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), to support a pending patent application for a machine that used a method for pouring glass into molds known as "gob feeding," officials and attorneys for Hartford "determined to have published in a trade journal an article signed by an ostensibly disinterested expert which would describe 'gob feeding' as a remarkable advance in the art of fashioning glass by machine." *Id.* at 240. In fact, "the Hartford lawyer was true author of the spurious publication." *Id.* at 241. After its publication, the article was submitted to the Patent Office in support of the application, which was then granted. *See id.* at 240–41. Hartford then brought an infringement action against Hazel, and in its successful appeal from the district's court's adverse ruling, Hartford stressed the importance of the supposedly independent article. *See id.* at 241. Although Hazel's attorneys were told at the time of the trial in the district court that the Hartford lawyer had admitted that he was the true author of the article, they did not pursue this suggestion at that time, and only obtained document-

ary proof of the fraud after the decision of the court of appeals had produced a settlement of the original infringement action favorable to Hartford. *See id.* at 242–43. At that point, Hazel commenced a new action seeking relief from the prior judgment on grounds of fraud. *See id.* at 243. Although the lower courts refused to grant relief, this Court reversed, holding that "[e]very element of the fraud here disclosed demands the exercise of the historic power of equity to set aside fraudulently begotten judgments." *Id.* at 245. The Court added that "even if Hazel had not exercised the highest degree of diligence Hartford's fraud cannot be condoned for that reason alone . . . . Surely it cannot be that the preservation of the integrity of the judicial process must always await upon the diligence of the litigants." *Id.* at 246.[2]

Hazel-Glass does not stand alone. This Court treated the propriety of an independent action seeking relief from a judgment procured by fraud

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[2] One aspect of *Hazel-Glass* is no longer good law. In a portion of the opinion that may well have been dicta, the Court observed that a judgment of a court of appeals may not be attacked in a district court until leave is granted by the appellate tribunal. *See* 322 U.S. at 248. This Court subsequently rejected an appellate-leave requirement. *See Standard Oil Co. of Cal. v. United States*, 429 U.S. 17 (1976) (per curiam). If anything, this subsequent development broadened the scope of the remedy recognized in *Hazel-Glass*, rather than casting any doubt on the soundness of the holding in that case on which we rely.

as settled as early as *Marshall v. Holmes*, 141 U.S. 589 (1891), in which the Court held that an action seeking relief from a judgment obtained by fraud should be treated as an independent action that may be brought in a federal court even if the underlying judgment was rendered by a state court. *See id.* at 596–601. The propriety of an independent action was reaffirmed as recently as *United States v. Beggerly*, 524 U.S. 38 (1998), in which the Court identified both the scope and the limitations on the doctrine: "[A]n independent actions should be available only to prevent a grave miscarriage of justice." *Id.* at 47.[3] Thus, as a leading treatise explains, an action for relief from a prior judgment "embrace[s] only that species of fraud which does or attempts to subvert the integrity of the court itself, or is a fraud perpetrated by officers of the court so that the judicial machinery cannot perform in the usual manner its impartial task of adjudging cases that are presented for adjudication." 7 JAMES W. MOORE *ET AL.*, MOORE'S FEDERAL PRACTICE ¶ 60.33, at 360 (2d ed. 1993); *accord, e.g.*, *Appling v. State Farm Mutual Automobile Insurance Co.*, 340 F.3d 769, 780 (9th Cir. 2003); *Hadges v. Yonkers Racing Corp.*, 48 F.3d 1320, 1325 (2d Cir. 1995); *Great Coastal Express, Inc. v. International Brotherhood of Teamsters*, 675 F.2d 1349, 1355–56 (4th Cir. 1982).

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[3] In that case, the Court held that when the evidence showed no more than that the United States failed to make a sufficiently thorough search of its records in the underlying litigation the threshold for an independent action was not satisfied. *See* 524 U.S. at 47.

A split in the circuits has developed about whether a district court's disposition of an independent action alleging that a prior judgment was obtained by fraud should be reviewed deferentially on appeal for abuse of discretion. The Eleventh Circuit, for example, treats the question of whether to entertain an independent action as entirely discretionary with the trial court, analogizing to the limited review of a district court's ruling on a motion for relief from judgment under Rule 60(b). *See Patterson v. Lew*, No. 07-13227, 2008 WL 382658, *1 (11th Cir., Feb. 13, 2008) ("We review a district court's dismissal of an independent action under FED. R. CIV. P. 60(b) for abuse of discretion."); *Booker v. Dugger*, 825 F.2d 281, 285 (11th Cir. 1987) ("Since Booker cannot offer clear and convincing evidence of fraud on the court, we conclude that the district court did not abuse its discretion in dismissing Booker's independent action under Rule 60(b)."). The Ninth Circuit likewise gives the district court discretion over whether even to entertain such an action. *See Appling*, 340 F.3d at 80 ("Accordingly, we hold that the district court did not abuse its discretion by dismissing the independent action."). The Sixth Circuit similarly applies the abuse of discretion standard to its review of any decision in an independent action, including the decision whether or not to entertain the action at all. *See Buell v. Anderson*, 48 Fed. Appx. 491, 498 (6th Cir. 2002) ("Because the independent action for relief sounds in equity, the appellate standard of review is abuse of discretion."); *Barrett v. Secretary of Health & Human Services*, 840 F.2d 1259, 1263 (6th Cir. 1987) ("Because this is an equitable action, our standard of review is abuse of discretion."). The Second Circuit

also vests the district court with discretion about whether even to entertain an independent action. *See Campaniello Imports, Ltd. v. Saporiti Italia S.p.A.*, 117 F.3d 655, 661 (2d Cir. 1997) ("The court exercises discretion in determining whether to entertain independent actions for relief and looks to traditional equitable principles to guide its decision").

The Third Circuit, in contrast, has held that a district court's ruling in an independent action is to be reviewed de novo, not for abuse of discretion. *See Herring v. United States*, 424 F.3d 384, 389 (3rd Cir. 2005). The court explained:

> Initially, we must be clear that we are not here reviewing a Rule 60 (b) motion. The provision of Rule 60(b) commonly known as the "savings clause" states: "**This rule does not limit the power of a court to entertain an independent action** to grant relief a party from a judgment, order, or proceeding, or to grant relief to a defendant not actually personally notified as provided in Title 28, U.S.C. § 1655, or to set aside a judgment for fraud upon the court. It follows that an independent action alleging fraud upon the court is completely distinct from a motion under Rule 60(b).
>
> We are similarly unpersuaded by the Government's argument that because Rule 60(b) allows relief more broad than an independent action for fraud upon the court, and determinations based on Rule

> 60(b) are reviewed only for abuse of discretion, an independent action for fraud upon the court should be reviewed at least as deferentially. Fundamentally, this argument confuses standard of review with burden of proof. We are quite capable of taking full account of the narrow criteria for relief present in an independent action for fraud upon the court without altering the Federal Rules of Civil Procedure. Under the normal *de novo* review that applies to a district court's grant of a Rule 12(b)(6) motion to dismiss for failure to state a claim, we can determine whether the Appellants have alleged facts which, if true, provide a basis for relief under the very demanding legal standard for fraud upon the court.

Id. (emphasis in original) (citations omitted).

In this case, the Federal Circuit lined up with those circuits that review a district court's ruling in an independent action alleging fraud in obtaining a judgment. The court wrote that "a district court's decision as to whether relief should be granted under rule 60(b) is committed to the sound discretion of the court," Pet. App. 8a, and under that standard affirmed the judgment of the district court on the ground that "the district court's finding that [Merck's process] was not abandoned, suppressed, or concealed was not shown to be error." Pet. App. 9a. The court even wrote that Apotex's suit was brought "pursuant to Federal Rule of Civil Procedure 60(b)(3)," Pet App. 1a, and referred to the

district court's proceedings as a consideration of "Apotex's motion." Pet. App. 8a. This case, however, was an independent action, not a Rule 60 proceeding. The court of appeals' decision to conflate the two is squarely inconsistent with the approach taken in *Herring*, in which the Third Circuit held that appellate review in independent actions for fraud should be judged under the same standards that are applicable in ordinary litigation rather than the special rules governing a motion for relief from judgment under Rule 60.

Had the court of appeals taken the approach to appellate review embraced by the Third Circuit in *Herring*, it would not have truncated its review as it did. Just as a district court's decision to dismiss a complaint is reviewed on appeal de novo under the rules that ordinarily govern appellate review in civil litigation, a summary judgment ruling also receives de novo review. *See, e.g.*, *Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451, 465 n.10 (1992); *Agosto v. INS*, 436 U.S. 748, 756–57 (1978). By placing the burden on Apotex to establish an abuse of discretion rather than assessing de novo whether the extensive evidentiary materials submitted by Apotex raised a genuine issue of material fact, the court of appeals in this case took an approach that the Third Circuit plainly would not countenance in an independent action for fraud.

Accordingly, this case presents a question on which the circuits are divided. There is, moreover, no likelihood that this split in the circuits will disappear without this Court's intervention in light of the Third Circuit's emphatic and quite recent opin-

ion in *Herring*. Plenary review is warranted to resolve this split in the circuits.

2. The approach of the Third Circuit in *Herring* is far more faithful to the nature of an independent action than the approach taken in the decision below, which wrongly conflates an independent action with a motion for relief from judgment under Rule 60.

The Federal Rules of Civil Procedure state that they "govern the procedure in all civil actions and proceedings in the United States district courts, except as stated in Rule 81." FED. R. CIV. PROC. 1. Rule 81, in turn, excepts specific proceedings from the scope of the rules, but does not identify independent actions seeking relief from a judgment obtained by fraud as one of the exceptions. *See* FED. R. CIV. PROC. 81.

Thus, the Federal Rules of Civil Procedure are no less applicable to independent actions seeking relief from a judgment obtained by fraud than any other form of civil litigation not exempted by Rule 81. Rule 56, in turn, provides that summary judgment is proper only when the record discloses no genuine issue of material fact. *See* FED. R. CIV. PROC. 56(c) ("The judgment sought should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law."); *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) ("The Federal Rules of Civil Procedure have for almost 50 years authorized motions for summary judgment upon proper showings of the

lack of a genuine, triable issue of material fact."); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) ("summary judgment will not lie if the dispute about a material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."); *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585–86 (1986) ("To survive petitioners' motion for summary judgment, respondents must establish that there is a genuine issue of material fact as to whether petitioners entered into an illegal conspiracy that caused respondents to suffer a cognizable injury."). Thus, the proper standard in summary judgment litigation in an independent action for fraud such as this case is whether the record raises a genuine issue of material fact. Moreover, as we explain above, it is equally settled that appellate review of a district court's summary judgment ruling is de novo.

To be sure, Rule 60 authorizes a litigant to file a motion seeking relief from judgment on the basis of fraud. *See* FED. R. CIV. PROC. 60(b)(3). Proceedings under Rule 60 are reviewed deferentially on appeal. *See Browder v. Director, Illinois Department of Corrections*, 434 U.S. 257, 263 n.7 (1978). To construe Rule 60 to limit the ability of a plaintiff in an independent action to obtain the benefit of the summary judgment standard, however, would be to ignore the savings clause in Rule 60, as the Third Circuit explained in *Herring*. Indeed, the terms of the savings clause could not be more plain: "This rule does not limit the power of a court to: (1) entertain an independent action to relieve a party from a judgment, order, or proceeding . . . . or (3) set aside a judgment for fraud on the court." FED.

R. CIV. PROC. 60(d). Thus, employing Rule 60 as a means of limiting the applicability of either Rule 56 or the requirement that summary judgment rulings be reviewed de novo on appeal is to violate the express terms of Rule 60(d). It follows that the approach taken by the Federal Circuit below is untenable.

Accordingly, the judgment below should not stand. At no point in its opinion did the district court assess the evidence adduced by Apotex under the correct standard – there is simply no inquiry into whether Apotex raised a genuine issue of material fact contained in the opinions below. And, as we explain above, the court of appeals expressly refused to engage in de novo review, relying instead on Rule 60 to support a more limited appellate review. Rule 60, however, cannot properly be construed to limit the applicability of Rule 56 and the standards governing summary judgment proceedings in the district court or on appeal.

Moreover, although, as we acknowledge above, in an independent action the plaintiff must establish particularly grave fraud, that is no reason to except such litigation from the standards that ordinarily govern motions for summary judgment. In ruling on a summary judgment motion the court should take into account the substantive burden of proof when assessing whether plaintiff has raised any genuine issue of material fact. *See, e.g.*, *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986) ("Thus, in ruling on a motion for summary judgment, the judge must view the evidence presented through the prism of the substantive evidentiary burden."). The district court, however,

never articulated the proper standard in summary judgment litigation, even in light of the demanding standard for establishing fraud in an independent action. And, in any event, the court of appeals wholly failed to employ de novo review, even if a de novo assessment would have been undertaken with reference to the standards for establishing fraud in an independent action.

3. Given the nature of the issue presented, the case for plenary review is especially compelling.

As this Court explained in *Hazel-Atlas*, the question whether a judgment is obtained by fraud "involves far more than injury to a single litigant." 322 U.S. at 346. Instead, the integrity of the administration of justice is at stake. We do not doubt that there is a potent judicial interest in promoting finality in litigation and avoiding the burdens of relitigation. The strong policy against relitigation is surely among the factors that have induced some courts to ignore the plain language of Rule 60's savings clause and employ that Rule as a means of limiting the scope of independent actions. That approach to Rule 60, however, not only turns the savings clause into meaningless surplusage, but it erodes the fundamental mission of the independent action as a means of preserving the integrity of the judicial process.

Dispositions should be not only "speedy" and "inexpensive", but also "just". Litigants should not be asked to pick two of three. In this case, Apotex alleged precisely the type of scheme that falls within the office of an independent action seeking relief from a judgment obtained by fraud – a

scheme by Merck to distort the factfinding process through false and misleading representations to the court utterly inconsistent with its posture in other litigation. Justice may often be better served by rules that promote finality in litigation, but as the line of cases recognizing the propriety of independent actions seeking relief from judgments procured by fraud recognize, at some point even the interest in finality cannot properly give succor to fraud. Plenary review is amply warranted here.

CONCLUSION

For the preceding reasons, the petition for a writ of certiorari should be granted.

Respectfully Submitted,

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March 27, 2008

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 2006-1405

APOTEX CORP.,

Plaintiff-Appellant,

v.

MERCK & CO., INC.,

Defendant-Appellee.

DECIDED: November 16, 2007

Before NEWMAN, RADER, and PROST, *Circuit Judges.*

NEWMAN, Circuit Judge.

Apotex Corp. appeals the decision of the United States District Court for the Northern District of Illinois[4] granting summary judgment in favor of Merck & Co. in an action by Apotex to set aside a judgment on charges of fraud, pursuant to FEDERAL RULE OF CIVIL PROCEDURE 60(b)(3). Apotex also asserted state law claims against Merck for common law fraud and tortious interference with prospective economic advantage, and sought to compel discovery pursuant to the crime fraud exception to the attorney-client privilege. The judgment of the district court is affirmed.

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[4] *Apotex Corp. v. Merck & Co.*, No. 04 C 7312, 2006 WL 1155954 (N.D. Ill. April 25, 2006) ("Apotex III").

BACKGROUND

In 1996 Apotex filed suit against Merck in the Northern District of Illinois, charging that Merck's process for formulating and producing tablets of the pharmaceutical compound enalapril (brand name VASOTEC®, used to treat high blood pressure) infringed Apotex's United States patents No. 5,573,780 and No. 5,690,962. The Apotex process involves the following steps, as set forth in claim 1 of the '780 patent:

> 1. A process of manufacture of a pharmaceutical solid composition comprising enalapril sodium, which process comprises the steps of:
>
> (i) (a) mixing enalapril maleate with an alkaline sodium compound and at least one other excipient, adding water sufficient to moisten, and mixing to achieve a wet mass, or
>
> (b) mixing enalapril maleate with at least one excipient other than an alkaline sodium compound, adding a solution of alkaline sodium compound in water, sufficient to moisten and mixing to achieve a wet mass;
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> thereby to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water;
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> (ii) drying the wet mass, and;
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> (iii) further processing the dried material into tablets.

The district court ruled in January 2000 that the Apotex patents were invalid under 35 U.S.C. § 102(g), on the ground that the process had been invented and used by Merck before Apotex made the invention set forth in the Apotex patents. *Apotex Corp. v. Merck & Co.*, No. 96 C 7375, 2000 WL 97582 (N.D. Ill. Jan. 25, 2000) (*Apotex I*). 35 U.S.C. § 102(g) provides that an applicant is not entitled to a patent if "before such person's invention thereof, the invention was made in this country by another, who had not abandoned, suppressed, or concealed it." The Federal Circuit affirmed. *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031 (Fed. Cir. 2001) (*Apotex II*).

In *Apotex I* and *Apotex II* it was generally undisputed that Merck had invented and practiced the accused process well before Apotex had done so, but Apotex argued that it was entitled to a patent because Merck had suppressed or concealed the invention and practiced it in secret, and therefore that Merck infringed the Apotex patents. The district court rejected the Apotex argument, finding that the process as practiced by Merck was not suppressed, concealed, or secret. The court found that well before the date that Apotex stated was its invention date, Merck had widely distributed a list of the ingredients in its tableted product. The district court referred to admissions from Apotex witnesses that "any chemist who knew the ingredients and knew that the process involved adding water to the mix would automatically know that a reaction of the enalapril malete occurred." *Apotex I*, 2000 WL 97582 at *8. In addition, in 1991 Merck's vice president of marketing, Brian McLeod, narrated a videotape describing the Merck process, presented during the

trial of a lawsuit in Canada in which Merck and its Canadian subsidiary had sued Apotex's Canadian affiliate for infringing Merck's Canadian patent on enalapril. The Federal Circuit affirmed the district court's ruling that the Apotex patents were invalid based on prior invention by another, deeming the narration at the Canadian trial to be a public disclosure of Merck's process. *Apotex II*, 254 F.3d at 1040. This court held that the various disclosures by Merck "made the knowledge of [Merck's] invention available to the public, thereby satisfying its burden of rebutting Apotex's evidence of suppression or concealment." *Id.*

More than one year later Apotex returned to the district court, charging that the district court's ruling in *Apotex I*, and our affirmance thereof in *Apotex II*, were obtained by fraud. Apotex charged that Merck had falsely stated, in its response to a discovery request, that "the entire process was publicly discussed in open court by Brian McLeod during the Canadian Litigation" and falsely stated that "[t]his process has not been abandoned, suppressed, or concealed." Apotex also charged that Merck misrepresented facts in its summary judgment brief submitted to the district court and in its appellate brief submitted to the Federal Circuit, and made false statements, *viz.*, the statements: "[t]he details of the process were the subject of public testimony in a court action in Canada"; Brian McLeod provided a "step by step explanation of Merck's process"; "one could reverse-engineer Merck's process by examining Merck's tablets and by reviewing the ingredient list"; "Merck disagrees that it ever suppressed or concealed the invention"; and

Merck's "conduct in the late 1980s and early 1990s belies any intention to keep its process secret."

Apotex argued that Merck admitted in 2004 that these statements were false, after *Apotex I* had been decided and affirmed, because Merck's key witness in *Apotex I*, Dr. Brenner, testified to the contrary in a different case in which he was an expert witness. That case was between Warner-Lambert Co. and Teva Pharmaceuticals USA, and involved quinapril, a related but different compound from enalapril. The district court did not agree with the Apotex position, finding that the aspects that Apotex stated established Merck's fraud concerned details of Merck's process for manufacturing enalapril, and not information claimed in or disclosed by the Apotex patent. The court explained that whether Merck had fully disclosed all of its own manufacturing details was irrelevant to the validity of the Apotex patents covering the process broadly. *Apotex III*, 2006 WL 1155954 at *7.

The district court also observed that various allegedly fraudulent statements were not testimony or evidence, but attorney argument, and concluded: "These statements, however, like those discussed previously, were statements made by Merck's attorneys concerning the reasonable inferences that could be drawn from the evidence uncovered during discovery. As such, they were not fraudulent and cannot form the basis of relief under Rule 60(b)." *Id.* As to the Apotex request to compel discovery of privileged communications between Merck and its attorneys, the court ruled that Apotex had made no showing sufficient to invoke the crime fraud excep-

tion to the attorney-client privilege. The district court also rejected the argument that it constituted fraud for Merck to have refrained from seeking patent protection for its process.

Apotex appeals the ruling that fraud had not been established. The state law claims were dismissed by the district court and are not appealed.

DISCUSSION

I

Federal Rule of Civil Procedure 60(b) states the conditions on which a court can set aside a judgment based on assertion of fraud:

> RULE 60(B) MISTAKES; INADVERTENCE; EXCUSABLE NEGLECT; NEWLY DISCOVERED EVIDENCE; FRAUD, ETC.
>
> On motion and upon such terms as are just, the court may relieve a party or a party's legal representative from a final judgment, order, or proceeding for the following reasons: (1) mistake, inadvertence, surprise, or excusable neglect; (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b); (3) fraud (whether heretofore denominated intrinsic or extrinsic), misrepresentation, or other misconduct of an adverse party; . . . or (6) any other reason justifying relief from the operation of judgment.

> The motion shall be made within a reasonable time, and for reasons (1), (2), and (3) not more than one year after the judgment, order, or proceeding was entered or taken. A motion under this subdivision (b) does not affect the finality of a judgment or suspend its operation. This rule does not limit the power of a court . . . to set aside a judgment for fraud upon the court.

Rule 60(b)(3) provides that a judgment can be set aside for fraud or misrepresentation only when the motion is made within a year after the judgment, unless there was "fraud upon the court" or other egregious act not previously uncovered.

Fraud upon the court requires that there was a material subversion of the legal process such as could not have been exposed within the one-year window; it requires rigorous proof, as do other challenges to final judgment, lest the finality established by Rule 60(b) be overwhelmed by continuing attacks on the judgment. *See Broyhill Furniture Indus. v. Craftmaster Furniture Corp.*, 12 F.3d 1080, 1085 (Fed. Cir. 1993) ("fraud upon the court should [] embrace only that species of fraud which does or attempts to subvert the integrity of the court itself, or is a fraud perpetuated by officers of the court so that the judicial machinery cannot perform in the usual manner its impartial task of adjudging cases that are presented for adjudication") (bracket in original, citations omitted). Fraud upon the court is typically limited to egregious events such as bribery of a judge or juror or improper influence exerted on the court,

affecting the integrity of the court and its ability to function impartially. *Id.* at 1085–86. Such issues are not subject to a one-year limitation, but must be raised within a reasonable time of discovery of the fraud. Similarly, the Seventh Circuit has ruled that a district court's decision as to whether relief should be granted under rule 60(b) is committed to the sound discretion of the court. *See, e.g., Nelson v. City Colleges of Chicago*, 962 F.2d 754, 755 (7th Cir. 1992) ("we have noted many times that '[t]he district courts are given wide latitude in declining motions under Rule 60(b)'"); *Matter of Whitney-Forbes, Inc.*, 770 F.2d 692, 698 (7th Cir. 1985) ("Fraud on the court involves a particular type of fraud which is directed to the judicial machinery itself, *Bulloch v. United States*, 721 F.2d 713, 718 (10th Cir. 1983), and which involves circumstances where the impartial functions of the court have been directly corrupted.").

In considering Apotex's motion, the district court divided into three groups the allegedly fraudulent statements that Merck was accused of having made in the previous litigation. The first group consisted of Merck's statements that it had publicly disclosed its entire process before the Apotex invention; the second group consisted of Merck's statements that its process could be reverse-engineered from the details that were disclosed; the third group consisted of Merck's statements that it did not suppress or conceal the process. The district court analyzed the statements of each group, and found that they did not constitute fraud. The court observed that if some aspect of Merck's witness presentation or attorney argument at the trial had been defective or over-stated, then Apotex should have

challenged it with contrary evidence and argument at the trial. It is apparent that Apotex had the opportunity to challenge Merck's position in the previous litigation, and indeed did so.

No error has been shown in the district court's analysis and conclusions. As the court observed, during discovery and trial in *Apotex I* Merck presented evidence that it was wet-granulating enalapril maleate with sodium bicarbonate and at least one excipient in the early 1980s. These ingredients were published in the *Dictionnaire Vidal* since at least 1985, as well as in promotional materials provided to pharmacists and doctors in Canada. The district court found, and it was not disputed, that this process had been used continuously in Merck's plants in the United States, since before Apotex's asserted date of conception of the same process. The Merck process was discussed in open court during the Canadian Litigation, and the district court's finding that it was not abandoned, suppressed, or concealed was not shown to be in error. The district court observed that "all of this occurred before the date of conception by the alleged inventor." *Apotex III*, 2006 WL 1155954 at *3. This court so observed in Apotex II:

> In 1991, Merck and its Canadian subsidiary, Merck Frosst Canada, Inc., sued Apotex's Canadian affiliate, Apotex Canada, for infringement of Merck's Canadian patent covering the enalapril sodium compound. [*Apotex I*] at *1. During the 1994 trial ("the Canadian trial"), Brian McLeod, Merck's then-vice president of marketing,

> performed a step-by-step narration of a videotape demonstrating Merck's process of manufacturing VASOTEC(R). *Id.* Within days of hearing this testimony, Dr. Bernard Sherman, an Apotex official, allegedly conceived the patented process at issue.

Id. 254 F.3d at 1034.

Apotex presses on this appeal that Merck had not disclosed in Canada five "critical" aspects of the invention: the type of mixing equipment used, the duration of mixing, the temperature of the water, the holding time after mixing, and the particle size of the sodium bicarbonate. Apotex also argues that Merck had not disclosed that the purpose of the sodium bicarbonate in the solution was to react with enalapril maleate to form enalapril sodium. Apotex argues that this withheld information proves that Merck had not "disclosed the entire process," as it claimed in its discovery response. The district court found that Apotex's argument failed to establish fraud upon the court because "the five critical factors cited by Apotex were not a part of Apotex's patented process." *Apotex III*, 2006 WL 1155954 at *4–5. We agree that Merck's processing details, which are not asserted to be invented by Apotex, did not warrant detailed disclosure, and that the presentation of the Merck process did not establish fraud on the court.

The various other aspects raised by Apotex relate to issues that were tried in 2000 and decided in *Apotex I*, and appealed and decided in 2001 in *Apotex II*. The district court correctly ruled that evidence

that was adduced and argument presented at the trial does not establish corruption of the judicial process. *See Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1550 (Fed. Cir. 1987) (fraud on the court "is fraud which is directed to the judicial machinery itself and is not fraud between the parties or fraudulent documents, false statements or perjury, [but] where the impartial functions of the court have been directly corrupted") (internal citations omitted).

The district court's denial of Apotex's motion to set aside the judgment in *Apotex I* for fraud upon the court, is affirmed.

II

Apotex also appeals the district court's refusal, in *Apotex I*, to compel discovery of material that was subject to the attorney-client privilege. Apotex argues that discovery of privileged material is available under the crime-fraud exception, and that since fraud was committed the privilege did not apply and therefore that Apotex was entitled to the requested discovery.

To obtain this exception to the privilege, Apotex must make a *prima facie* showing of some foundation for the asserted fraud. *See Clark v. United States*, 289 U.S. 1, 15 (1993) (loss of attorney-client privilege requires prima facie evidence that the charge of fraud has "some foundation in fact"). Apotex states that Merck's counsel made fraudulent statements during the litigation, as discussed *ante*. The district court found that the accused statements were simply attorney argument as to the inferences to be drawn

from the evidence, and that falsity was not shown. We agree that Apotex has not made a *prima facie* showing that fraud was committed, and that the district court did not abuse its discretion in refusing to compel discovery of material protected by the attorney-client privilege.

AFFIRMED

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

APOTEX CORP.,

Plaintiff,

vs.

MERCK & CO., INC.,

Defendant.

Case No. 04 C 7312

MEMORANDUM OPINON AND ORDER

MATTHEW F. KENNELLY, *District Judge.*

Apotex Corp. has sued Merck & Co., alleging that Merck obtained a favorable judgment in an earlier case, in which Apotex had sued Merck for patent infringement, by making a number of fraudulent representations to this Court. Apotex has filed an action in which it asks the Court to vacate the judgment in the previous case pursuant to FEDERAL RULE OF CIVIL PROCEDURE 60(b)(3) (Count 1) and also asserts state law claims against Merck for common law fraud (Count 2) and tortious interference with prospective economic advantage (Count 3). Merck has moved for summary judgment. For the following reasons, the Court grants Merck's motion.

FACTS

The resolution of this motion is the latest chapter in Apotex's prolonged attempt to establish the validity of two patents (Nos. 5,573,780 and 5,690,962) that cover a process for making a pharmaceutical compound used to treat high blood pressure. The process involves the following steps:

> 1. A process of manufacture of a pharmaceutical solid composition comprising enalapril sodium, which process comprises the steps of:
>
> (i) (a) mixing enalapril maleate with an alkaline sodium compound and at least one other excipient, adding water sufficient to moisten, and mixing to achieve a wet mass, or
>
> (b) mixing enalapril maleate with at least one excipient other than an alkaline sodium compound, adding a solution of alkaline sodium compound in water, sufficient to moisten and mixing to achieve a wet mass;
>
> thereby to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water;
>
> (ii) drying the wet mass, and;
>
> (iii) further processing the dried material into tablets.

See '780 Patent. The Court ruled in January 2000 that the claim required a "virtually complete" reaction of the active ingredient, enalapril maleate. *See Apotex Corp. v. Merck & Co., Inc.*, No. 96 C 7375,

2000 WL 97582, *3 (N.D. Ill. Jan. 25, 2000) (*Apotex I*).

Apotex originally sued Merck for patent infringement in 1996, and after the case was reassigned to this Court's docket in June 1999, we ruled in January 2000 that Merck had infringed the patents but that the patents were invalid under 35 U.S.C. § 102(g). *Id.* at *5, 8. Section 102(g) provides that an applicant is not entitled to a patent if "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it."

In the previous case, the parties agreed that Merck invented the allegedly infringing process long before Apotex conceived of the idea. Apotex maintained, however, that its patents were valid because Merck had suppressed or concealed the invention. The Court rejected Apotex's argument, relying on evidence that prior to the date of Apotex's alleged invention, Merck had widely distributed a list of ingredients found in its product and that Merck's vice president of marketing, Brian McLeod, narrated a videotape describing the process during the trial of a lawsuit in Canada. The Court also relied on admissions from Apotex witnesses that "any chemist who knew the ingredients and knew that the process involved adding water to the mix would automatically know that a reaction of the enalapril malete occurred." *See id.* at *8. The Federal Circuit affirmed this Court's ruling. *See Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1040 (Fed. Cir. 2001).

Apotex now maintains that the Court's January 2000 ruling as well as the Federal Circuit's June 2001 ruling were obtained by fraud. Specifically, Apotex claims that Merck falsely responded to a discovery request seeking "all facts and documents" supporting its allegations of patent invalidity by stating that "the entire process was publicly discussed in open court by Brian McLeod during the Canadian Litigation" and that "[t]his process has not been abandoned, suppressed, or concealed." Apotex Mem. at 2–3. Apotex also claims that Merck misrepresented facts in its summary judgment brief submitted to this Court and in its brief submitted to the Federal Circuit. It points to Merck's statements in those briefs that "[t]he details of the process were the subject of public testimony in a court action in Canada"; Brian McLeod provided a "step by step explanation of Merck's process"; "one could reverse engineer Merck's process by examining Merck's tablets and by reviewing the ingredient list"; "Merck disagrees that it ever suppressed or concealed the invention"; and Merck's "conduct in the late 1980s and early 1990s belies any intention to keep its process secret." *See id.*

Apotex contends that Merck admitted the untruth of these statements in 2004 when its key witness in the 2000 case, Dr. Brenner, testified as follows in a different case:

- "The 'lynch pin' [sic] of Merck's process for making stable enalapril tablets was the conversion of enalapril maleate to enalapril sodium, and the key factor in the stabilization of enalapril tablets was the extent to which

this reaction went to completion." *Apotex Mem.* at 3.

- A number of factors played important roles in the stabilization process, including "the type of mixing equipment, the duration and temperature of the mixing, the holding time in the mixing equipment after mixing, and the particle size of sodium bicarbonate." *Id.*

- Merck's Canadian demonstration did not disclose that Merck was converting enalapril maleate to enalapril sodium, the above listed factors, or the need to have a complete or virtually complete reaction. *Id.*

- The process for making enalapril tablets could not be reverse engineered because it would be difficult to determine that there was enalapril sodium in Merck's VASOTEC® tablets. *Id.* at 4.

- "Merck decided to maintain as a trade secret the critical process steps for reacting enalapril maleate and sodium bicarbonate to produce enalapril sodium in the wet granulation rather than seeking patent protection for the process." *Id.*

- Merck had maintained the critical role of sodium bicarbonate in its process a trade secret until December 1994. *Id.*

- Merck never disclosed its actual process for making VASOTEC® until May 2004. *Id.*

On July 22, 2005, Apotex moved to compel the production of documents that included the thoughts and impressions of the attorneys who participated in the earlier case. Merck objected to the request on the basis of attorney-client privilege, but Apotex contended that this privilege had been waived because Merck used the attorney-client relationship to perpetuate a fraud. The Court denied Apotex's motion, concluding that Apotex had not made a prima facie showing of fraud. *Apotex Inc. v. Merck & Co., Inc.*, 229 F.R.D. 142, 147 (N.D. Ill. 2005). The Court said that Merck's purported fraudulent statements were nothing more than its attorney's reasonable inferences from the evidence as it existed in the record. *Id.* at 148.

DISCUSSION

Apotex's motion involves two Federal Rules of Civil Procedure: Rule 56(c) and Rule 60(b)(3). Rule 56(c) says that a motion for summary judgment shall be granted "if the pleadings depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." In considering a motion for summary judgment, the Court views the facts in the light most favorable to the nonmoving party and draws reasonable inferences in its favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

Rule 60(b)(3) allows a court to "relieve a party or a party's legal representative from a final judgment, order, or proceeding for the following reasons: . . . (3) fraud (whether heretofore denomi-

nated intrinsic or extrinsic), misrepresentation, or other misconduct of an adverse party. "Under this rule, "the victim of the fraud . . . need show only that it affected his ability to present his case, not that he would have won had the fraud or misconduct not occurred." *Ty Inc. v. Softbelly's Inc.*, 353 F.3d 528, 536 (7th Cir. 2003). At the same time, a court will not relieve a party from a final judgment if the alleged misrepresentations were not relevant to the theory on which the district court based its decision. *See Williams v. U.S. Drug Enforcement Admin.*, 51 F.3d 732, 736 (7th Cir. 1995). Fraud must be shown by clear and convincing evidence. *See Ty Inc.*, 353 F.3d at 537. Motions under Rule 60(b)(3), even when they involve patent cases, are resolved according to regional circuit law. *See Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198, 1204–05 (Fed Cir. 2005).

Apotex has pointed to three different groups of fraudulent statements that it contends require the Court to grant Apotex relief from judgment. The first group involves statements in which Merck allegedly said that it publicly disclosed its entire process, the second group involves statements in which Merck allegedly said that one could reverse engineer Merck's process, and the third group involves statements in which Merck allegedly said that it never suppressed its invention. We examine each group of statements in turn.

1. "[T]he entire process was publicly discussed"

During discovery in *Apotex I*, Apotex served Merck with Interrogatory No. 17, which asked

Merck to identify "all facts and documents" that supported Merck's allegation of patent invalidity. Merck responded as follows:

> Merck was wet granulating enalapril maleate with sodium bicarbonate and at least one excipient in the early 1980s. This process has not been abandoned, suppressed, or concealed. These ingredients were clearly published in the Dictionnaire Vidal since at least 1985. The ingredients were also published on numerous promotional materials provided to pharmacists and doctors in Canada. The formulation process has been used continuously in Merck's plants in the United States. Moreover, the entire process was publicly discussed in open court by Brian McLeod during the Canadian Litigation. All of this occurred before the date of conception by the alleged inventor.

Apotex's L.R. 56.1 Stmt. of Add'l Facts ¶ 3. Apotex contends that Merck's statement was fraudulent because Merck had not disclosed "the entire process" by 1994. Specifically, Apotex says, Merck had not disclosed five critical factors used to perfect the stabilization of the product: the type of mixing equipment used, the duration of mixing, the temperature of the water, the holding time after mixing, and the particle size of the sodium bicarbonate. Apotex contends that Merck had also not disclosed that the purpose of sodium bicarbonate in the solution was to react with enalapril maleate to form enalapril sodium.

Apotex's argument is premised on a faulty assumption. It assumes that when Merck was referring to a "process" in its response to Interrogatory 17, it was referring to the entire process, from start to finish, used by Merck to make its VASOTEC® tablets. Read in context, however, it is clear that Merck was referring not to the VASOTEC® process in its entirety, but rather to the process described in the first sentence of the interrogatory answer: the process of "wet granulating enalapril maleate with sodium bicarbonate and at least one excipient"— the process patented by Apotex. In short, read in context, no reasonable fact finder could conclude that the response to Interrogatory 17 was false or fraudulent and certainly could not conclude that this had been shown by clear and convincing evidence: the five critical factors cited by Apotex were not a part of Apotex's patented process.

Apotex contends that even if the word "process" is understood to include only those processes listed in Apotex's patent, it was nevertheless dishonest for Merck to assert that it had disclosed the "entire process" because Merck had not disclosed the fact that its process "combined enalapril maleate and sodium bicarbonate in a manner that created enalapril sodium[ ] and failed to disclose the fact that the reaction between the two had to be complete or mostly complete." *Apotex Mem.* at 16. This argument is a partial rehashing of an argument that was previously resolved in the Court's January 2000 ruling, where we stated as follows:

> To the extent Apotex is implying that in 1983 Merck was hiding the fact

that its process involved reacting enalapril maleate to form a more stable enalapril sodium compound, that time frame is irrelevant. The relevant time frame for purposes of § 102(g) is when the later inventor conceives of his invention-in this case, some time between March 30, 1994 and April 19, 1994. By that time, Merck had fully disclosed the ingredients and the process. Plus, even Apotex's witnesses agreed that any chemist who knew the ingredients and knew that the process involved adding water to the mix would automatically know that a reaction of the enalapril maleate occurred. Dr. Richard McKeag, a scientist who worked with Dr. Sherman at Apotex Canada, testified that "[i]t was so simple that it was obvious; any chemist would know that, if you added bicarbonate or carbonate to a solution containing enalapril maleate, you would get the formation of the salt. You would get a chemical reaction to form a salt." McKeag Deposition Transcript, at 41. He also testified that "if you take sodium bicarbonate and put it into water and you have enalapril maleate in the same solution, it will react virtually spontaneously and irreversibly to form a new compound, to form enalapril sodium and disodium maleate." *Id.* at 46. Finally, he testified that "any chemist who looks at enalapril maleate would automatically assume its going to react with three moles of sodium bicarbonate if they are placed together in

> solution or in slurry or whatever, anything wet." *Id.* at 47. In short, what Apotex characterizes as "rank suppression and concealment" would not have fooled anyone-or at least anyone with a fundamental knowledge of chemistry.

See Apotex I, 2000 WL 97582 at *8. As this excerpt reflects, Apotex contended during the original summary judgment briefing in this case that Merck had not disclosed the presence of enalapril sodium in its tablets. Thus, Apotex was well aware of this purported misrepresentation during the previous litigation and was fully capable of bringing it to the Court's attention. As a result, the statement cannot constitute a basis for relief under Rule 60(b). *See Oxxford Clothes XX, Inc. v. Expeditors Int'l of Wash., Inc.*, 127 F.3d 574, 578 (7th Cir. 1997) (denying relief under Rule 60(b) where party was aware of alleged misrepresentations during previous litigation).

Insofar as Apotex contends that Merck's "entire process" statement was fraudulent because Merck had not disclosed that the enalapril reaction needed to be "virtually complete," the Court again concludes that this argument was available to Apotex during the previous litigation. McLeod's presentation in the Canadian lawsuit and the VASOTEC® ingredient list has been available to Apotex since at least May 1994. If there was an aspect of Apotex's process that Apotex felt Merck had not publicly disclosed-such as the virtual completeness of the reaction-then Apotex was free to argue that point to the Court in the previous litigation. As a result, Apotex has failed to offer

evidence that Merck's response to Interrogatory 17 requires the Court to grant relief under Rule 60(b).

Apotex also argues that Merck made fraudulent statements in the briefs submitted to this Court and the Federal Circuit that "[t]he details of the process were the subject of public testimony in a court action in Canada"; that "McLeod provided a visual, step by step explanation of Merck's process"; and that McLeod's presentation "was so detailed that it would allow one to understand Merck's process." First, as discussed above, if there was some aspect of Apotex's patented process-some "detail" or "step"— that Apotex believed Merck did not publicly disclose through McLeod's presentation in Canada, then Apotex had every opportunity to present this argument in the previous litigation and cannot now claim Merck committed a fraud on the court. Second, as discussed in more detail below, these statements were not responses to discovery requests or deposition testimony offered by Merck. Rather, they were permissible arguments based on the evidence and were therefore not fraudulent.

2. "One could reverse engineer Merck's process by examining Merck's tablets and by examining Merck's tablets and by reviewing the ingredient list in the Product Monograph."

Apotex next contends that Merck made a fraudulent statement on page forty-four of its brief filed in the Federal Circuit. There Merck argued, based on the testimony of Apotex's inventor Dr. Sherman, that "one could reverse engineer Merck's process by examining Merck's tablets and

by reviewing the ingredient list in the Product Monograph." Apotex maintains that this statement was fraudulent because Merck's Dr. Brenner admitted in 2004 that one could not "practice the process" simply by examining the tablets and reviewing the ingredients list.

As with the statement by Merck discussed in the previous section, Apotex takes this argument about reverse engineering completely out of context. In the two paragraphs immediately preceding the "reverse engineering" statement, Merck's brief recounts several parts of Dr. Sherman's testimony in which he stated that he determined that VASOTEC® tablets were prepared through a wet granulation process simply by examining them; after learning the ingredients in the tablets, he concluded that only Merck's actual process was probable; and tests he performed on the tablets revealed that they contained enalapril sodium. After recounting this testimony, Merck's brief goes on to conclude, "Thus one could reverse engineer Merck's process by examining Merck's tablets and by reviewing the ingredient list."

As noted in the Court's June 29, 2005 ruling on the attorney-client privilege issue, "the lawyer's statements in Merck's briefs were not an attempt to characterize the truth as an omniscient observer might see it." *Apotex Inc.*, 229 F.R.D. at 147. Rather, the "reverse engineering" statement was a reasonable inference that could be drawn from the evidence revealed during discovery, specifically, from the statements made by Dr. Sherman. As the Court concluded in its previous ruling, "It was not a 'fraud' for Merck to argue the inferences from the

evidence that had been presented in the case — even if it now turns out that the evidence that was presented might not have represented the full story." *Id.*

Apotex has not offered evidence that it made discovery requests concerning whether Merck's process could be "reverse engineered," nor has it offered evidence that Merck responded dishonestly to any such requests. Instead, Apotex's argument amounts to a contention that Merck failed to disclose voluntarily evidence that may have undercut the statement it made in its appellate brief-a statement, that was, again, a reasonable inference based on the evidence produced during discovery. Mere nondisclosure by a party or a party's attorney in a civil case does not amount to a fraud upon the court. *See* 11 CHARLES A. WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE & PROCEDURE § 2870 (1995); *Wilson v. Johns-Mansville Sales Corp.*, 873 F.2d 869, 872 (5th Cir. 1989) (declining to grant plaintiffs' 60(b) motion when defendants successfully used a "state of the art" defense in a products liability trial and plaintiffs later learned of studies, of which the defendants were aware, that undercut the defendants' theory). For these reasons, Apotex has not offered evidence that Merck's statements in its appellate brief require the Court to grant relief under Rule 60(b).

3. "Merck disagrees that it ever suppressed or concealed the invention"

Apotex's last group of purportedly fraudulently statements relate to the alleged suppression of Merck's process. Apotex points to a statement in

Merck's response to Interrogatory No. 17, in which it said, "This process has not been abandoned, suppressed, or concealed"; a statement in Merck's summary judgment brief in which it argued, "Merck disagrees that it ever suppressed or concealed the invention"; and a statement in Merck's appellate brief in which it argued, "Merck's conduct in the late 1980s and early 1990s belies any intention to keep its process secret." Apotex maintains that Dr. Brenner effectively showed these statements were untrue when he testified in 2004 that Merck decided to maintain the role of sodium bicarbonate in its process a trade secret until the late 1980s or early 1990s and that part of the discussion relating to that decision was the fact that the process could not be discerned simply by knowing the ingredients contained in the VASOTEC® tablet.

With regard to Merck's response to Interrogatory 17, in which Merck said the "process ha[d] not been abandoned, suppressed, or concealed," Apotex has again taken a single sentence out of context in an attempt to support its contention that fraud occurred. In this response, Merck first asserted that the process had not been suppressed. Then, in support of this contention, it asserted that the VASOTEC® ingredients had been published in the 1980s and that Apotex's claimed process was publicly discussed during the Canadian litigation on March 28, 1994. Thus, Merck was only asserting that it had not suppressed the process after March 28, 1994. Read this way, Dr. Brenner's testimony, in 2004, that Merck had suppressed the role of sodium bicarbonate in its process until the early 1980s or 1990s, is not evidence from which a fact finder could conclude that Merck's response to Interroga-

tory 17 was fraudulent, let alone by clear and convincing evidence.

Even if Merck had fraudulently asserted that it had not suppressed the process before March 28, 1994, however, this fact would not have been material to the Court's previous ruling. The time period relevant to the Court's suppression analysis was the period after March 30, 1994.[5] *See Apotex 1*, 254 F.3d at 1040 ("though Merck may have suppressed or concealed the process for a period of time . . ., as long as it 'resumed activity' (*i.e.*, made the benefits of its invention known to the public) before Apotex's entry into the field, it cannot be deemed to have suppressed or concealed [it]."); *Apotex I*, 2000 WL 97582 at *8 ("To the extent Apotex is implying that in 1983 Merck was hiding [its process], that time frame is irrelevant. The relevant time frame for purposes of 102(g) is when the later inventor conceives of his invention — in this case, some time between March 30, 1994 and April 30, 1994."). Misrepresentations that are immaterial to the legal issues upon which a district court decides a case cannot form the basis for relief under Rule 60(b). *See Simons v. Gorsuch*, 715 F.2d 1248, 1253 (7th Cir. 1983).[6]

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[5]Apotex has not offered any evidence — let alone clear and convincing evidence — from which a fact finder could determine that Merck suppressed its process (i.e., the process patented by Apotex) after March 28, 1994.

[6]Apotex argues that Merck's alleged misrepresentations concerning the suppression of its process

Apotex also contends that Merck made fraudulent assertions in its summary judgment and appellate briefs, in which it stated that "Merck disagrees that it ever suppressed or concealed the invention," and that "Merck's conduct in the late 1980s and early 1990s belies any intention to keep its process secret." These statements, however, like those discussed previously, were statements made by Merck's attorneys concerning the reasonable inferences that could be drawn from the evidence uncovered during discovery. As such, they were not fraudulent and cannot form the basis of relief under Rule 60(b). *See supra* at 9–10.

The cases cited by Apotex do not call for a different result. In *Hazel-Atlas Glass Oil Co. v. Hartford-Empire Co.*, 322 U.S. 238, 246 (1944), the Court held that a patent attorney committed fraud on the court when he fabricated a trade journal article to obtain a patent and then to establish the validity of the patent in the court of appeals. In *Pumphrey v. K.W. Thompson Tool Co.*, 62 F.3d 1128, 1131 (9th Cir. 1995), the court held that the

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must have been relevant because another court, in *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, No. Civ.A. 99-922DRD, 2004 WL 1498162, *20 (D.N.J. June 29, 2004), ruled that Merck's suppression of its process was relevant. In *Warner-Lambert*, however, the plaintiff's patented process was conceived not in March 1994, but in August 1986. *Id.* Consequently, the court's ruling does not demonstrate that Merck's alleged suppression of its process prior to March 30, 1994 is relevant in this case.

defendant committed fraud on the court when he deliberately concealed damaging evidence that the plaintiff had specifically requested during discovery. Apotex has not offered evidence that Merck deliberately withheld or fabricated evidence in the previous litigation.

4. Apotex's expert testimony

Apotex offers expert testimony from two distinguished legal scholars in support of its argument that Merck committed fraud during the underlying litigation. Merck contends that this testimony is inadmissible because it offers opinions on whether Merck committed a fraud. The admission of expert testimony is governed by Federal Rule of Evidence 702 and the principles set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). According to the Seventh Circuit, the Court first must determine whether the expert's testimony is reliable by assessing whether the expert is qualified in the relevant field and by examining the expert's methodology. *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). The Court must then determine if the expert's testimony will assist the trier of fact in understanding the evidence or determining a fact at issue in the case. *Id.* at 721. Though Rule 704 of the Federal Rules of Evidence allows experts to opine on "ultimate issues to be decided by the trier of fact," the testimony must still assist the fact finder to reach a decision on a particular issue in controversy.

The Seventh Circuit has held that legal conclusions that will determine the outcome of a case are inadmissible expert testimony. *See Good*

Shepherd Manor Found., Inc. v. City of Chicago, 323 F.3d 557, 564 (7th Cir. 2003). In addition, several judges in this district, including this Court, have held that expert testimony is not helpful to a trier of fact when the expert simply opines that an individual acted dishonestly or fraudulently, issues traditionally resolved by a trier of fact. *See Ass'n Benefit Svcs. v. AdvancePCS Holding Corp.,* No. 04 C 3271, 2005 WL 2335484, *4 (N.D. Ill. Sept. 23, 2005) (holding that expert could not testify about ultimate issue of defendant's fraudulent intent); *Klackzak v. Consolidated Med. Transp., Inc.,* No. 96 C 6502, 2005 WL 1564981, *8, 10 (N.D. Ill. May 26, 2005) (holding that expert could not testify that defendants committed fraud within the meaning of the Anti-Kickback statute); *Dahlin v. Evangelical Child & Family Agency,* No. 01 C 1182, 2002 WL 31834881, *3 (N.D. Ill. Dec. 18, 2002) (excluding expert testimony that the defendant's employees acted dishonestly).

Much of Apotex's expert testimony — which reads more like a legal brief than an expert report — consists of plainly inadmissible legal conclusions concerning Merck's alleged fraud and would be completely unhelpful to the fact finder. *See* Ex. E ¶ 36 ("It is my opinion based on the evidence that . . . Merck's conduct . . . [was] a fraud on the courts."); Ex. F ¶ 58 ("In my view, the fraud perpetrated on this court in *Apotex I* was more serious that the misconduct that occurred in that leading Supreme Court case"). The Court, not an expert, must determine whether Merck's statements rise to the level of fraud under Rule 60(b), and the fact finder, not an expert, must determine whether Apotex has offered evidence that Merck committed

common law fraud. Because Apotex has not shown how these experts' testimony would assist us in doing so, the testimony is inadmissible under Rule 702.

5. State law claims

Apotex has also asserted state law claims for common law fraud and tortious interference with prospective economic advantage. Apotex premises both claims, however, on the theory that "this Court invalidated Apotex's patents based on Merck's false assertions." *See Apotex Mem.* at 22. Because the Court has already concluded that Apotex has not offered evidence from which a reasonable fact finder could conclude that Merck made material misrepresentations in the previous litigation, Merck is entitled to summary judgment on these claims as well. *See Rauenhorst v. United States,* 104 F.R.D. 588, 603 (D. Minn. 1985) (dismissing plaintiff's common law fraud claims that were based on the same alleged misstatements that formed the basis of plaintiff's 60(b) motion).

CONCLUSION

For the reasons stated above, the Court grants defendant's motion for summary judgment [docket no. 71]. The Clerk is directed to enter judgment in favor of the defendant.

APPENDIX C

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 2006-1405

APOTEX CORP.,

Plaintiff-Appellant,

v.

MERCK & CO., INC.,

Defendant-Appellee.

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellant, and the petition for rehearing, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service.

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED,

The mandate of the court will issue on January 4, 2008.

Circuit Judge Schall did not participate in the vote.

FOR THE COURT,
/s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 12/28/2007

cc: Robert B. Breisblatt
Nicolas G. Barzoukas

APOTEX V MERCK, 2006-1405
(DCT - 04-CV-7312)

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

DEC 28 2007

JAN HORBALY
CLERK

APPENDIX D
FED. R. CIV. PROC. 60 (EFF. DEC. 1, 2007). WITH COMMENTS

Rule 60. Relief from Judgment or Order.

(a) CORRECTIONS BASED ON CLERICAL MISTAKES; OVERSIGHTS AND OMISSIONS. The court may correct a clerical mistake or a mistake arising from oversight or omission whenever one is found in a judgment, order, or other part of the record. The court may do so on motion or on its own, with or without notice. But after an appeal has been docketed in the appellate court and while it is pending, such a mistake may be corrected only with the appellate court's leave.

(b) GROUNDS FOR RELIEF FROM A FINAL JUDGMENT, ORDER, OR PROCEEDING. On motion and just terms, the court may relieve a party or its legal representative from a final judgment, order, or proceeding for the following reasons:

(1) mistake, inadvertence, surprise, or excusable neglect;

(2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b);

(3) fraud (whether previously called intrinsic or extrinsic), misrepresentation, or misconduct by an opposing party;

(4) the judgment is void;

(5) the judgment has been satisfied, released, or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or

(6) any other reason that justifies relief.

(c) TIMING AND EFFECT OF THE MOTION.

(1) Timing. A motion under Rule 60(b) must be made within a reasonable time — and for reasons (1), (2), and (3) no more than a year after the entry of the judgment or order or the date of the proceeding.

(2) Effect on Finality. The motion does not affect the judgment's finality or suspend its operation.

(d) OTHER POWERS TO GRANT RELIEF. This rule does not limit a court's power to:

(1) entertain an independent action to relieve a party from a judgment, order, or proceeding;

(2) grant relief under 28 U.S.C. § 1655 to a defendant who was not personally notified of the action; or

(3) set aside a judgment for fraud on the court.

(e) BILLS AND WRITS ABOLISHED. The following are abolished: bills of review, bills in the nature of bills of review, and writs of coram nobis, coram vobis, and audita querela.

(As amended Dec. 27, 1946, eff. Mar. 19, 1948; Dec. 29, 1948, eff. Oct. 20, 1949; Mar. 2, 1987, eff. Aug. 1, 1987; Apr. 30, 2007, eff. Dec. 1, 2007.)

ADVISORY COMMITTEE NOTES

1937 Adoption

Note to Subdivision (a). *See* [former] Equity Rule 72 (Correction of Clerical Mistakes in Orders and Decrees); Mich. Court Rules Ann. (Searl, 1933) Rule 48, § 3; 2 Wash. Rev. Stat. Ann. (Remington, 1932) § 464(3); Wyo. Rev. Stat. Ann. (Courtright, 1931) § 89-2301(3). For an example of a very liberal provision for the correction of clerical errors

and for amendment after judgment, see Va.Code Ann. (Michie, 1936) §§ 6329, 6333.

Note to Subdivision (b). Application to the court under this subdivision does not extend the time for taking an appeal, as distinguished from the motion for new trial. This section is based upon Calif. Code Civ. Proc. (Deering, 1937) § 473. *See also* N.Y.C.P.A. (1937) § 108; 2 Minn. Stat. (Mason, 1927) § 9283.

For the independent action to relieve against mistake, etc., *see* Dobie, Federal Procedure, pages 760 to 765, *compare* 639; and Simkins, Federal Practice, ch. CXXI (pp. 820 to 830) and ch. CXXII (pp. 831 to 834), compare § 214.

1946 Amendment

Note. Subdivision (a). The amendment incorporates the view expressed in *Perlman v. 322 West Seventy-Second Street, Co., Inc.*, C.C.A.2d, 1942, 127 F.2d 716; 3 Moore's Federal Practice, 1938, 3276, and further permits correction after docketing, with leave of the appellate court. Some courts have thought that upon the taking of an appeal the district court lost its power to act. *See Schram v. Safety Investment Co.*, E.D. Mich. 1942, 45 F. Supp. 636; *also Miller v. United States*, C.C.A.7th, 1940, 114 F.2d 267.

Subdivision (b). When promulgated, the rules contained a number of provisions, including those found in Rule 60(b), describing the practice by a motion to obtain relief from judgments, and these rules, coupled with the reservation in Rule 60(b) of the right to entertain a new action to relieve a party from a judgment, were generally supposed to cover the field. Since the rules have been in force,

decisions have been rendered that the use of bills of review, coram nobis, or audita querela, to obtain relief from final judgments is still proper, and that various remedies of this kind still exist although they are not mentioned in the rules and the practice is not prescribed in the rules. It is obvious that the rules should be complete in this respect and define the practice with respect to any existing rights or remedies to obtain relief from final judgments. For extended discussion of the old common law writs and equitable remedies, the interpretation of Rule 60, and proposals for change, see Moore and Rogers, *Federal Relief from Civil Judgments*, 1946, 55 Yale L.J. 623. See also 3 Moore's Federal Practice, 1938, 3254 et seq.; Commentary, *Effect of Rule 60b on Other Methods of Relief From Judgment*, 1941, 4 Fed. Rules Serv. 942, 945; *Wallace v. United States*, C.C.A.2d, 1944, 142 F.2d 240, *certiorari denied*, 65 S.Ct. 37, 323 U.S. 712, 89 L.Ed. 573.

The reconstruction of Rule 60(b) has for one of its purposes a clarification of this situation. Two types of procedure to obtain relief from judgments are specified in the rules as it is proposed to amend them. One procedure is by motion in the court and in the action in which the judgment was rendered. The other procedure is by a new or independent action to obtain relief from a judgment, which action may or may not be begun in the court which rendered the judgment. Various rules, such as the one dealing with a motion for new trial and for amendment of judgments, Rule 59, one for amended findings, Rule 52, and one for judgment notwithstanding the verdict, Rule 50(b), and including the provisions of Rule 60(b) as amended, prescribe the various types of cases in which the practice by motion is permitted. In each case there

is a limit upon the time within which resort to a motion is permitted, and this time limit may not be enlarged under Rule 6(b). If the right to make a motion is lost by the expiration of the time limits fixed in these rules, the only other procedural remedy is by a new or independent action to set aside a judgment upon those principles which have heretofore been applied in such an action. Where the independent action is resorted to, the limitations of time are those of laches or statutes of limitations. The Committee has endeavored to ascertain all the remedies and types of relief heretofore available by coram nobis, coram vobis, audita querela, bill of review, or bill in the nature of a bill of review. See Moore and Rogers, Federal Relief from Civil Judgments, 1946, 55 Yale L.J. 623, 659 to 682. It endeavored then to amend the rules to permit, either by motion or by independent action, the granting of various kinds of relief from judgments which were permitted in the federal courts prior to the adoption of these rules, and the amendment concludes with a provision abolishing the use of bills of review and the other common law writs referred to, and requiring the practice to be by motion or by independent action.

To illustrate the operation of the amendment, it will be noted that under Rule 59(b) as it now stands, without amendment, a motion for new trial on the ground of newly discovered evidence is permitted within ten days after the entry of the judgment, or after that time upon leave of the court. It is proposed to amend Rule 59(b) by providing that under that rule a motion for new trial shall be served not later than ten days after the entry of the judgment, whatever the ground be for the motion, whether error by the court or newly

discovered evidence. On the other hand, one of the purposes of the bill of review in equity was to afford relief on the ground of newly discovered evidence long after the entry of the judgment. Therefore, to permit relief by a motion similar to that heretofore obtained on bill of review, Rule 60(b) as amended permits an application for relief to be made by motion, on the ground of newly discovered evidence, within one year after judgment. Such a motion under Rule 60(b) does not affect the finality of the judgment, but a motion under Rule 59, made within 10 days, does affect finality and the running of the time for appeal.

If these various amendments, including principally those to Rule 60(b), accomplish the purpose for which they are intended, the federal rules will deal with the practice in every sort of case in which relief from final judgments is asked, and prescribe the practice. With reference to the question whether, as the rules now exist, relief by coram nobis, bills of review, and so forth, is permissible, the generally accepted view is that the remedies are still available, although the precise relief obtained in a particular case by use of these ancillary remedies is shrouded in ancient lore and mystery. See Wallace v. United States, C.C.A.2d, 1944, 142 F.2d 240, certiorari denied 65 S.Ct. 37, 323 U.S. 712, 89 L.Ed. 573; Fraser v. Doing, App.D.C.1942, 130 F.2d 617; Jones v. Watts, C.C.A.5th, 1944, 142 F.2d 575; Preveden v. Hahn, S.D.N.Y.1941, 36 F.Supp. 952; Cavallo v. Agwilines, Inc., S.D.N.Y.1942, 6 Fed.Rules Serv. 60b.31, Case 2, 2 F.R.D. 526; McGinn v. United States, D.C.Mass.1942, 6 Fed.Rules Serv. 60b.51, Case 3, 2 F.R.D. 562; City of Shattuck, Oklahoma ex rel. Versluis v. Oliver, W.D.Okl.1945, 8 Fed.Rules Serv. 60b.31, Case 3;

Moore and Rogers, Federal Relief from Civil Judgments, 1946, 55 Yale L.J. 623, 631 to 653; 3 Moore's Federal Practice, 1938, 3254 et seq.; Commentary, Effect of Rule 60b on Other Methods of Relief From Judgment, op. cit. supra. Cf. Norris v. Camp, C.C.A.10th, 1944, 144 F.2d 1; Reed v. South Atlantic Steamship Co. of Delaware, D.Del.1942, 2 F.R.D. 475, 6 Fed.Rules Serv. 60b.31, Case 1; Laughlin v. Berens, D.D.C.1945, 8 Fed.Rules Serv. 60b.51, Case 1, 73 W.L.R. 209.

The transposition of the words "the court" and the addition of the word "and" at the beginning of the first sentence are merely verbal changes. The addition of the qualifying word "final" emphasizes the character of the judgments, orders or proceedings from which Rule 60(b) affords relief; and hence interlocutory judgments are not brought within the restrictions of the rule, but rather they are left subject to the complete power of the court rendering them to afford such relief from them as justice requires.

The qualifying pronoun "his" has been eliminated on the basis that it is too restrictive, and that the subdivision should include the mistake or neglect of others which may be just as material and call just as much for supervisory jurisdiction as where the judgment is taken against the party through his mistake, inadvertence, etc.

Fraud, whether intrinsic or extrinsic, misrepresentation, or other misconduct of an adverse party are express grounds for relief by motion under amended subdivision (b). There is no sound reason for their exclusion. The incorporation of fraud and the like within the scope of the rule also removes confusion as to the proper procedure. It has been held that relief from a judgment obtained by ex-

trinsic fraud could be secured by motion within a "reasonable time," which might be after the time stated in the rule had run. Fiske v. Buder, C.C.A.8th, 1942, 125 F.2d 841; see also inferentially Bucy v. Nevada Construction Co., C.C.A.9th, 1942, 125 F.2d 213. On the other hand, it has been suggested that in view of the fact that fraud was omitted from original Rule 60(b) as a ground for relief, an independent action was the only proper remedy. Commentary, Effect of Rule 60b on Other Methods of Relief From Judgment, 1941, 4 Fed.Rules Serv. 942, 945. The amendment settles this problem by making fraud an express ground for relief by motion; and under the saving clause, fraud may be urged as a basis for relief by independent action insofar as established doctrine permits. See Moore and Rogers, Federal Relief from Civil Judgments, 1946, 55 Yale L.J. 623, 653 to 659; 3 Moore's Federal Practice, 1938, 3267 et seq. And the rule expressly does not limit the power of the court, when fraud has been perpetrated upon it, to give relief under the saving clause. As an illustration of this situation, see Hazel-Atlas Glass Co. v. Hartford Empire Co., 1944, 64 S.Ct. 997, 322 U.S. 238, 88 L.Ed. 1250.

The time limit for relief by motion in the court and in the action in which the judgment was rendered has been enlarged from six months to one year.

It should be noted that Rule 60(b) does not assume to define the substantive law as to the grounds for vacating judgments, but merely prescribes the practice in proceedings to obtain relief. It should also be noted that under § 200(4) of the Soldiers' and Sailors' Civil Relief Act of 1940, § 501 et seq. [§ 520(4)] of the Appendix to Title 50, a

judgment rendered in any action or proceeding governed by the section may be vacated under certain specified circumstances upon proper application to the court.

1948 Amendment

The amendment effective October, 1949 substituted the reference to "Title 28, U.S.C. § 1655," in the next to the last sentence of subdivision (b), for the reference to "Section 57 of the Judicial Code, U.S.C., Title 28, § 118".

1987 Amendment

The amendment is technical. No substantive change is intended.

2007 Amendments

The language of Rule 60 has been amended as part of the general restyling of the Civil Rules to make them more easily understood and to make style and terminology consistent throughout the rules. These changes are intended to be stylistic only.

The final sentence of former Rule 60(b) said that the procedure for obtaining any relief from a judgment was by motion as prescribed in the Civil Rules or by an independent action. That provision is deleted as unnecessary. Relief continues to be available only as provided in the Civil Rules or by independent action.

APPENDIX E
FED. R. CIV. PROC. 60 (EFF. AUG. 1, 1987).

Rule 60. Relief from Judgment or Order.

(a) CLERICAL MISTAKES. Clerical mistakes in judgments, orders or other parts of the record and errors therein arising from oversight or omission may be corrected by the court at any time of its own initiative or on the motion of any party and after such notice, if any, as the court orders. During the pendency of an appeal, such mistakes may be so corrected before the appeal is docketed in the appellate court, and thereafter while the appeal is pending may be so corrected with leave of the appellate court.

(b) MISTAKES; INADVERTENCE; EXCUSABLE NEGLECT; NEWLY DISCOVERED EVIDENCE; FRAUD, ETC. On motion and upon such terms as are just, the court may relieve a party or a party's legal representative from a final judgment, order, or proceeding for the following reasons: (1) mistake, inadvertence, surprise, or excusable neglect; (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b); (3) fraud (whether heretofore denominated intrinsic or extrinsic), misrepresentation, or other misconduct of an adverse party; (4) the judgment is void; (5) the judgment has been satisfied, released, or discharged, or a prior judgment upon which it is based has been reversed or otherwise vacated, or it is no longer equitable that the judgment should have prospective application; or (6) any other reason justifying relief from the operation of the judgment. The motion shall be made within a reasonable time, and

for reasons (1), (2), and (3) not more than one year after the judgment, order, or proceeding was entered or taken. A motion under this subdivision (b) does not affect the finality of a judgment or suspend its operation. This rule does not limit the power of a court to entertain an independent action to relieve a party from a judgment, order, or proceeding, or to grant relief to a defendant not actually personally notified as provided in Title 28, U.S.C., § 1655, or to set aside a judgment for fraud upon the court. Writs of coram nobis, coram vobis, audita querela, and bills of review and bills in the nature of a bill of review, are abolished, and the procedure for obtaining any relief from a judgment shall be by motion as prescribed in these rules or by an independent action.

(As amended Dec. 27, 1946, eff. Mar. 19, 1948; Dec. 29, 1948, eff. Oct. 20, 1949; Mar. 2, 1987, eff. Aug. 1, 1987.)

APPENDIX F
U.S. DIST. CT. N.D. IL. LOCAL RULE 56.1

Rule 56.1. Motions for Summary Judgment

(a) MOVING PARTY. With each motion for summary judgment filed pursuant to Fed. R. Civ. P. 56 the moving party shall serve and file —

(1) any affidavits and other materials referred to in Fed. R. Civ. P. 56(e);

(2) a supporting memorandum of law; and

(3) a statement of material facts as to which the moving party contends there is no genuine issue and that entitle the moving party to a judgment as a matter of law, and that also includes:

(A) a description of the parties, and

(B) all facts supporting venue and jurisdiction in this Court.

The statement referred to in (3) shall consist of short numbered paragraphs, including within each paragraph specific references to the affidavits, parts of the record, and other supporting materials relied upon to support the facts set forth in that paragraph. Failure to submit such a statement constitutes grounds for denial of the motion.

If additional material facts are submitted by the opposing party pursuant to section (b), the moving party may submit a concise reply in the form prescribed in that section for a response. All material facts set forth in the statement filed pursuant to section (b)(3)(B) will be deemed admitted unless controverted by the statement of the moving party.

(b) OPPOSING PARTY. Each party opposing a motion filed pursuant to Fed. R. Civ. P. 56 shall serve and file —

. (1) any opposing affidavits and other materials referred to in Fed. R. Civ. P. 56(e);

(2) a supporting memorandum of law; and

(3) a concise response to the movant's statement that shall contain:

(A) a response to each numbered paragraph in the moving party's statement, including, in the case of any disagreement, specific references to the affidavits, parts of the record, and other supporting materials relied upon, and

(B) a statement, consisting of short numbered paragraphs, of any additional facts that require the denial of summary judgment, including references to the affidavits, parts of the record, and other supporting materials relied upon. All material facts set forth in the statement required of the moving party will be deemed to be admitted unless controverted by the statement of the opposing party.

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(2)

No. 07-1238

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APR 30 2007
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IN THE

Supreme Court of the United States

APOTEX CORP.,

Petitioner,

v.

MERCK & CO., INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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QUESTION FOR REVIEW

Whether Petitioner Apotex has presented compelling reasons to grant the Petition, where the Federal Circuit affirmed the District Court's rejection of Apotex's independent action under Fed. R. Civ. P. 60(b) under the abuse of discretion standard of review, an approach consistent with the standard of review applied by the Federal Circuit and other circuits.

CORPORATE DISCLOSURE STATEMENT

No parent or publicly held company owns 10% or more of Respondent Merck & Co., Inc.'s stock.

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I. INTRODUCTION

Petitioner Apotex Corp. ("Apotex") wrongfully accused Respondent Merck & Co., Inc. ("Merck") and its attorneys of fraud on the court in an earlier patent litigation, during which two Apotex patents were held invalid.[1] In this litigation, Apotex sought relief from the earlier judgment through an independent action under Fed. R. Civ. P. 60(b) ("Rule 60(b)") in a suit brought in the Northern District of Illinois. The district court found that Apotex presented no evidence that Merck or its attorneys did anything improper in the earlier litigation, and entered summary judgment in Merck's favor.[2] Under the abuse of discretion standard of review that applies to Rule 60(b) actions, a unanimous panel of the Federal Circuit affirmed. Apotex's petition for rehearing and rehearing *en banc* was denied.

Merck respectfully urges this Court to deny Apotex's petition for writ of *certiorari* ("Petition"). First, Apotex's Petition is incorrectly premised upon a supposed split among the circuits about the appellate standard of review for Rule 60(b) independent actions. Yet the only

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[1] *Apotex USA, Inc. v. Merck & Co., Inc.*, 254 F.3d 1031 (Fed. Cir. 2001).

[2] The district court also denied Apotex's attempt to intrude into Merck's privileged information from the earlier litigation under the crime-fraud exception. *Apotex Corp. v. Merck & Co., Inc.*, 229 F.R.D. 142 (N.D.Ill 2005). The Federal Circuit panel unanimously affirmed, and Apotex's Petition does not seek review of that decision. As the Federal Circuit held, Apotex could not even establish a *prima facie* case of fraud. *Apotex Corp. v. Merck & Co., Inc.*, 507 F.3d 1357, 1362 (Fed. Cir. 2007).

evidence Apotex offers of this "split" is misapplication of a Third Circuit opinion, in which the court performed *de novo* review of the district court's dismissal of a case under Fed. R. Civ. P. 12(b)(6). Second, considering Apotex presented no evidence that Merck and its attorneys acted improperly in the earlier litigation, the Federal Circuit would also have been compelled to affirm under the *de novo* standard of review.

II. STATEMENT OF THE CASE

A. Merck Publicly Disclosed the Process Claimed by the Invalid Apotex Patents Before Apotex's Dr. Bernard Sherman "Conceived" It

Merck scientists invented the pharmaceutical compound enalapril for the treatment of high blood pressure, and developed a process for making enalapril tablets in the early 1980s.[3] Merck began using the manufacturing process at least as early as 1983, and sold enalapril tablets made by this process since 1986 under the trademark VASOTEC® in the United States.[4]

Merck publicly disclosed the ingredients used in its VASOTEC® tablet process in at least two publications: the 1988 edition of the French pharmaceutical reference publication *Dictionnaire Vidal*, and the 1992 Canadian product circular for VASOTEC® tablets.[5]

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[3] *Apotex USA, Inc. v. Merck & Co., Inc.*, 254 F.3d 1031, 1034 (Fed. Cir. 2001).

[4] *Id.*

[5] *Id.*

Merck then publicly disclosed how to mix the ingredients. Merck and its Canadian affiliate Merck Frosst Canada, Inc. sued Apotex's Canadian affiliate Apotex, Inc. in Canada for infringing Merck's Canadian patent that covered enalapril.[6] During the Canadian litigation, Merck's VASOTEC® tablet process was the subject of public testimony. On March 28, 1994, Mr. Brian McLeod, then Vice-President of Marketing for Merck Frosst, presented a tutorial accompanied by a videotape in open court that disclosed how Merck mixed the ingredients in its VASOTEC® tablet process.[7]

Thus, as of March 28, 1994, Merck had publicly disclosed the ingredients used in its VASOTEC® tablet process (the 1988 *Dictionnaire Vidal* and the 1992 Canadian product circular) and how to mix them (McLeod's testimony).[8] By that time, Merck's VASOTEC® tablets made by this process had also been available to patients for about eight years.

But on August 4, 1995, Apotex filed a United States patent application naming Apotex's President and CEO Dr. Bernard Sherman as the inventor of a process using ingredients and methods identical to those publicly described by Merck. Apotex eventually obtained two United States patents. Apotex asserted both patents against Merck in the United States District Court for the Northern District of Illinois ("*Apotex I*").

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[6] *Id.*

[7] *Id.*

[8] *Id.*

In *Apotex I*, Apotex admitted that Sherman "conceived" the invention claimed by the Apotex patents no earlier than March 30, 1994 (*i.e.*, two days after McLeod's public testimony at the Canadian Apotex trial).

The district court in *Apotex I* held on summary judgment that Merck's public disclosures invalidated Apotex's patents.[9] Apotex's patents were invalid under 35 U.S.C. § 102(g), which provides that "[a] person shall be entitled to a patent unless . . . (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed or concealed it." A unanimous panel of the Federal Circuit affirmed, even while presuming that Merck initially maintained its VASOTEC® tablet process as a trade secret:

> Thus, even though **Merck may have suppressed or concealed the process** for a period of time after it reduced it to practice in 1983, as long as it "resumed activity" (*i.e.*, made the benefits of its invention known to the public) before Apotex's entry into the field, it cannot be deemed to have suppressed or concealed the invention within the meaning of § 102(g).
>
> **Merck made several disclosures following its period of suppression or concealment**

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[9] *Apotex Corp. v. Merck & Co., Inc.*, 2000 WL 97582 (N.D.Ill. 2000). The district court also denied Apotex's motion for reconsideration. *Apotex Corp. v. Merck & Co., Inc.*, 2000 WL 656670 (N.D.Ill. 2000).

> **that made the invention publicly known, all of which took place before Apotex's entry into the field (here, Dr. Sherman's alleged conception in April of 1994).** First, Merck disclosed the ingredients used in manufacturing VASOTEC® tablets in the 1988 edition of the Dictionnaire Vidal. It also widely distributed the product monograph in Canada from October 1992 through 1994, which similarly disclosed the ingredients it used in its manufacturing process. Merck also provided a step-by-step description of the process through the testimony given by Brian McLeod at the Canadian trial on March 28, 1994.

Apotex USA, Inc. v. Merck & Co., Inc., 254 F.3d 1031, 1040 (Fed. Cir. 2001) (emphasis added). The Federal Circuit rejected Apotex's petition for rehearing and rehearing *en banc*. Finally, this Court denied Apotex's petition for writ of *certiorari*.[10]

B. Absent Evidence of Fraud, Apotex Has Focused Upon Relitigating *Apotex I*

In May 2004, former Merck scientist Dr. Gerald Brenner testified as an expert witness at a trial for a case in which the Warner-Lambert Company sued Teva Pharmaceuticals USA, Inc. for infringement of a Warner-Lambert patent related to quinapril, a medicinal

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[10] *Apotex USA, Inc. v. Merck & Co., Inc.*, 534 U.S. 1172 (2002).

compound similar to enalapril.[11] Dr. Brenner testified about additional details of Merck's optimized VASOTEC® tablet process, including parameters that were neither disclosed nor claimed by the invalid Apotex patents (and therefore, not at issue in *Apotex I*). Apotex obtained full discovery about these additional parameters in *Apotex I*. Dr. Brenner also testified that Merck might have maintained aspects of its optimized VASOTEC® tablet process as a trade secret, albeit well before Merck had publicly disclosed the ingredients and how to mix them.

Nevertheless, based upon nothing but Brenner's testimony during the *Warner-Lambert* case, Apotex filed the current case ("*Apotex II*") against Merck, seeking relief under Rule 60(b) to have the *Apotex I* judgment set aside based upon alleged fraud. But in *Apotex II*, Apotex has not presented any evidence that Merck and its attorneys did anything improper in *Apotex I*. Accordingly, the district court once again granted summary judgment in favor of Merck. The district court considered Dr. Brenner's testimony during the *Warner-Lambert* case and determined "Apotex has not offered any evidence – much less clear and convincing evidence – from which a fact finder could determine that Merck suppressed its process (*i.e.*, the process patented by Apotex) after March 28, 1994."[12] The district court also

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[11] *See Warner-Lambert Company v. Teva Pharmaceuticals USA, Inc.*, 2004 WL 1498162 (D.N.J. 2004); 418 F.3d 1326 (Fed. Cir. 2005).

[12] *Apotex Corp. v. Merck & Co., Inc.*, 2006 WL 1155954, fn. 1 (N.D.Ill. 2006).

observed "Apotex has not offered evidence that Merck deliberately withheld or fabricated evidence [*e.g.*, the public disclosures of the *Dictionnaire Vidal*, the Canadian product circular, or McLeod's Canadian demonstration] in the previous litigation."[13]

Again, a unanimous panel of the Federal Circuit affirmed under the abuse of discretion standard of review that applies to Rule 60(b) actions. As the Federal Circuit explained when it reviewed Dr. Brenner's testimony from the *Warner-Lambert* case, "Merck's processing details, which are not asserted to be invented by Apotex, did not warrant detailed disclosure, and that the presentation of the Merck process did not establish fraud on the court."[14] Dr. Brenner's testimony during the *Warner-Lambert* case did not establish fraud, and "the district court's finding [in *Apotex II*] that it [the patent process] was not abandoned, suppressed or concealed [under 35 U.S.C. § 102(g)] was not shown to be in error."[15] Indeed, the Federal Circuit held that Apotex had not even made a *prima facie* case of fraud.[16]

The indisputable fact that Apotex presented no evidence of fraud makes this case quite clear. Apotex's

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[13] *Apotex Corp. v. Merck & Co., Inc.*, 2006 WL 1155954, *7 (N.D.Ill. 2006).

[14] *Apotex Corp. v. Merck & Co., Inc.*, 507 F.3d 1357, 1362 (Fed. Cir. 2007).

[15] 507 F.3d at 1361.

[16] 507 F.3d at 1362.

Petition presents no compelling reasons for its grant, and is nothing more than a desperate attempt for Apotex to establish the validity of its patents.

III. SUMMARY OF THE ARGUMENT

Merck respectfully urges this Court to deny Apotex's Petition, which is premised upon nothing more than its disagreement with the Federal Circuit's review of the district court's judgment in *Apotex II* for abuse of discretion. Apotex wrongly argues that there is a "split" among the circuits on the standard of review for actions under Rule 60(b), yet the only evidence Apotex presents of this "split" is its misapplication of a Third Circuit opinion. The Federal Circuit's review for abuse of discretion was correct.

Regardless, the Federal Circuit would also have been compelled to affirm under the *de novo* standard of review. The district court found that Apotex offered no evidence that Merck and its attorneys did anything improper in *Apotex I*. The Federal Circuit would also have affirmed under the *de novo* standard because no evidence of fraud exists.

IV. ARGUMENT

A. There is No "Circuit Split" on the Standard of Review for Rule 60(b) Actions

An independent action seeks equitable relief from a previous judgment under Rule 60(b), and is granted only for injustices that are deemed sufficiently gross to demand a departure from rigid adherence to the

doctrine of *res judicata*. *United States v. Beggerly*, 524 U.S. 38, 46 (1998). Relief "should be available only to prevent a grave miscarriage of justice." *Id.*

This Court has held that appellate review of a district court's denial of equitable relief occurs under the abuse of discretion standard. *Brotherhood of Locomotive Engineers v. Missouri-Kansas-Texas RR Co.*, 363 U.S. 528 (1960). And a Rule 60(b) action seeks equitable relief from a previous judgment. Accordingly, the Federal Circuit properly reviewed the district court's denial of Apotex's Rule 60(b) independent action under the abuse of discretion standard that applies to such actions seeking equitable relief.

The Seventh Circuit has consistently held that review of a district court's denial of relief under Rule 60(b) occurs under the abuse of discretion standard.[17]

> The general rule in this circuit is that relief from a judgment under rule 60(b) is an extraordinary remedy granted only in exceptional circumstances. The decision to grant relief under rule 60(b) is left to the sound discretion of the trial court, and review of a trial court's decision to grant or deny rule 60(b) relief is subject to an abuse of discretion standard.

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[17] The Rule 60(b) analysis, even in a patent case like this, is resolved according to regional circuit law. *See Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198, 1204-05 (Fed. Cir. 2005).

United States v. Zima, 766 F.2d 1153, 1156 (7th Cir. 1985). *See also C.K.S. Engineers, Inc.*, 726 F.2d 1202, 1204-05 (7th Cir. 1984); *Brickwood Contractors, Inc. v. U.S.*, 288 F.3d 1371, 1376 (Fed. Cir. 2002). This deferential standard of review is appropriate given that "relief from a judgment under rule 60(b) is an extraordinary remedy and is granted only in exceptional circumstances." 766 F.2d at 1157.

As even Apotex admits, the Second, Sixth, Ninth, Eleventh, and Federal Circuits all hold that review of Rule 60(b) actions occurs under the abuse of discretion standard.[18] But Apotex then attempts to concoct a "circuit split" through misapplication of the Third Circuit's opinion in *Herring v. United States*, 424 F.3d 384 (3rd Cir. 2005). In *Herring*, the plaintiff alleged that the United States had committed fraud in an earlier litigation, and sought to have the judgment from the earlier litigation set aside through a Rule 60(b) independent action. The case ended when the district court granted the Government's Fed. R. Civ. P. 12(b)(6) motion to dismiss because the plaintiff had not alleged sufficient facts to meet the rigorous standards of Rule 60(b). On appeal, the Third Circuit reviewed under the *de novo* standard that applies to review of Fed. R. Civ. P. 12(b)(6) motions to dismiss.[19] Of course, if the Third

[18] Petition at 12-13.

[19] 424 F.3d at 389 ("Under the normal *de novo* review that applies to a district court's grant of a Rule 12(b)(6) motion to dismiss for failure to state a claim, we can determine whether the Appellants have alleged facts which, if true, provide a basis for relief under the very demanding legal standard for fraud upon the court.")

Circuit in *Herring* were instead reviewing the district court's disposition of the Rule 60(b) allegations on the merits (*i.e.*, disposition on the merits of an action seeking equitable relief), the Third Circuit would have instead reviewed under the abuse of discretion standard. *See Brotherhood of Locomotive Engineers v. Missouri-Kansas-Texas RR Co.*, 363 U.S. 528 (1960) (district court denial of equitable relief is reviewed for abuse of discretion).

Apotex's argument for a *de novo* standard of review would create an absurd result. Rule 60(b) motions, which must be brought within one year of judgment, are reviewed under the abuse of discretion standard. Yet in Apotex's view, Rule 60(b) independent actions, which seek the same type of relief as Rule 60(b) motions[20] and are brought one year after judgment, should instead be reviewed under the *de novo* standard. It should not be easier to seek Rule 60(b) relief a year after entry of judgment through an independent action, than it would be through a motion brought within a year after judgment. If Apotex were correct, it would become easier to strike down a judgment as time progressed, contrary to the principle of finality of judgment.[21]

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[20] *See Landau & Cleary, Ltd. v. Hribar Trucking, Inc.*, 867 F.2d 996, 1000 (7th Cir. 1989)("In other words, a proper 'independent action' must seek the same type of relief one seeks under Rule 60(b).")

[21] Rule 60(b) relief is granted only for injustices that are deemed sufficiently gross to demand a departure from rigid adherence to the doctrine of *res judicata*. *United States v. Beggerly*, 524 U.S. 38, 46 (1998).

B. The Federal Circuit Would Have Also Affirmed Under the *De Novo* Standard

Apparently, Apotex believes that under the less deferential *de novo* standard of review, the Federal Circuit would have reversed the district court's rejection of Apotex's Rule 60(b) independent action. Again, Apotex is wrong. Because there is no evidence of fraud, the Federal Circuit would have also been compelled to affirm under the *de novo* standard.

The district court and the Federal Circuit made it quite clear that there is no evidence that Merck and its attorneys had done anything improper in *Apotex I*. As the district court explained in its *Apotex II* opinion:

> Apotex has not offered any evidence – much less clear and convincing evidence – from which a fact finder could determine that Merck suppressed its process (*i.e.*, the process patented by Apotex) after March 28, 1994.[22]
>
> * * * * *
>
> Apotex has not offered evidence that Merck deliberately withheld or fabricated evidence [e.g., the public disclosures of the Dictionnaire Vidal, the Canadian product circular, or McLeod's Canadian demonstration] in the previous litigation.[23]

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[22] *Apotex Corp. v. Merck & Co., Inc.*, 2006 WL 1155954, fn. 1 (N.D.Ill. 2006).

[23] *Apotex Corp. v. Merck & Co., Inc.*, 2006 WL 1155954, *7 (N.D.Ill. 2006).

And in the Federal Circuit's affirmance, the Federal Circuit noted that Apotex could not even establish a *prima facie* case of fraud.[24]

Establishing fraud upon the court under Rule 60(b) requires "egregious . . . conduct that might be thought to corrupt the judicial process itself, as where a party bribes a judge or inserts bogus documents into the record." *Oxxford Clothes XX, Inc. v. Expediters Int'l of Washington, Inc.*, 127 F.3d 574, 578 (7th Cir. 1997). In *Apotex II*, no evidence of any fraud exists (much less, evidence of a false document or bribing a judge), and the Federal Circuit would have been compelled to affirm under any standard of review.

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[24] *Apotex Corp. v. Merck & Co., Inc.*, 507 F.3d 1357, 1362 (Fed. Cir. 2007).

V. CONCLUSION

For all these reasons, Merck respectfully requests that Apotex's Petition be DENIED.

Respectfully submitted,

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APOTEX CORP.,
Petitioner,

v.

MERCK & CO., INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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CORPORATE DISCLOSURE STATEMENT

As stated in the petition, and pursuant to this Court's Rule 29.6, petitioner Apotex Corporation states that it is a corporation organized and existing under the laws of the state of Delaware with its principal place of business in Weston, Florida and is a subsidiary of Aposherm, Inc., a corporation organized and existing under the laws of Canada. No publicly traded company owns 10% or more of Apotex's stock.

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Supreme Court Rule 29.6 i

IN THE

Supreme Court of the United States

APOTEX CORP.,

Petitioner,

v.

MERCK & CO., INC.,

Respondent.

Merck's Brief in Opposition ("Br.") contains quite astonishing mischaracterizations of the Third Circuit's decision in *Herring v. United States*, 424 F.3d 384 (3d Cir. 2005), and this Court's decision in *Brotherhood of Locomotive Engineers v. Missouri-Kansas-Texas R.R. Co.*, 363 U.S. 528 (1960). When these are put aside, it is plain that this case merits plenary review.

1. Merck observes that *Herring* involved a motion to dismiss a complaint in an independent action seeking relief from a judgment on the basis of fraud, and while acknowledging that the Third Circuit "reviewed [the district court's decision] under the *de novo* standard" (Br. 10) claims that "if the Third Circuit in *Herring* were instead reviewing the district court's disposition of the Rule 60(b) allegations on the merits (*i.e.*, disposition of the merits of an action seeking equitable relief), the Third Circuit would have instead reviewed under the abuse of discretion standard." *Id.* at 10–11. This account — conflating as it does an independent action with a motion for relief from

judgment under FED. R. CIV. P. 60(b) — cannot be reconciled with *Herring* itself.

In *Herring*, the court took pains to note that "an independent action alleging fraud on the court is completely distinct from a motion under Rule 60(b)." 424 F.3d at 389. For that reason, the court rejected the argument that because "determinations based on Rule 60(b) are reviewed only for abuse of discretion, an independent action for fraud should be reviewed at least as deferentially." *Id.* Instead, the court held that independent actions should be adjudicated "without altering the Federal Rules of Civil Procedure," and therefore employed "the normal *de novo* review that applies to a district court's grant of a Rule 12(b)(6) motion to dismiss . . . ." *Id.* This case involves review of a district court's summary judgment ruling, rather than a motion to dismiss, but as we explain in the petition, it is settled that summary judgment rulings, like rulings on a motion to dismiss, are reviewed *de novo* on appeal. (*See* Pet. 15.) Thus, *Herring* calls for *de novo* review here because that is the ordinary approach to review of summary judgment rulings under the Federal Rules of Civil Procedure. The more limited review of a Rule 60(b) ruling, *Herring* explains, has no place in an independent action.

Accordingly, it is evident that if a litigant in the Third Circuit forwarded Merck's argument that appellate review of a summary judgment ruling in an independent action alleging fraud on the court should be governed by Rule 60(b) standards, that litigant would be stopped short by *Herring*'s refusal to apply Rule 60(b) standards to independent

actions. While, as we acknowledge in the petition, a number of circuits, including the court below, have conflated Rule 60(b) motions and independent actions, the Third Circuit has emphatically refused to do so. (*See* Pet. 12–15.) The conflict in the circuits is patent.

2. Merck claims that *Brotherhood of Locomotive Engineers* settled that "appellate review of a district court's denial of equitable relief occurs under the abuse of discretion standard." (Br. 9.) This is a truly remarkable misuse of that decision.

In *Brotherhood of Locomotive Engineers*, the respondent railroads unilaterally altered their work rules, and, after a hearing, the district court enjoined the resulting strike pending a hearing before the National Railroad Adjustment Board but required the railroads to either rescind the changes or pay the affected employees the wages they would have received under the old rules. *See Brotherhood of Locomotive Engineers v. Missouri-Kansas-Tex R. Co.*, 363 U.S. 528, 529–30 (1960). In that context, the Court wrote: "The balancing of . . . competing claims of irreparable hardship is . . . the traditional function of the equity court, the exercise of which is reviewable only for abuse of discretion." *Id.* at 534–35. This holding was unremarkable; a long line of cases holds that a district court has broad discretion in fashioning equitable relief that is reviewable on appeal only for abuse of discretion. *See, e.g., eBay, Inc. v. Mercexchange, L.L.C.*, 547 U.S. 388, 391 (2006). But, as should be plain, Merck's reliance on *Brotherhood of Locomotive Engineers* in this case is doubly inapposite — *Brotherhood of Locomotive Engineers* involved the

scope of a district court's discretion when granting equitable relief, not denying it, and it dealt with the deference owed a district court's decision to fashion a remedy after an evidentiary hearing, not with the standard applicable to review of a district court's summary judgment ruling.

As we explain in the petition, it is settled that a district court's decision to grant summary judgment is reviewed on appeal *de novo*. (*See* Pet. 15.) Nothing in *Brotherhood of Locomotive Engineers* — which was simply not a summary judgment case — is inconsistent with this rule, nor is there any exception to the rule of *de novo* appellate review of summary judgment for cases seeking equitable relief. Indeed, one of the cases we cite on this point in the petition involved a request for equitable relief — *Agosto v. INS*, 436 U.S. 748 (1978), was an action to set aside an order of deportation. *See id.* at 750–52. This is but one of many cases applying *de novo* appellate review to summary judgment rulings in actions seeking equitable relief. *See, e.g.*, *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962) (action alleging a merger violated section 7 of the Clayton Act). There is simply no support for Merck's assertion that summary judgment rulings are reviewed deferentially in actions seeking equitable relief.

In any event, even if Merck were correct that summary judgment rulings in actions seeking equitable relief should be reviewed deferentially on appeal, this case was not confined to a request for equitable relief. Apotex's complaint contained common law fraud and tortious interference with business relationship counts and expressly sought

damages. Docket Item 26, *First Amended Complaint* at 13–16, (N.D. Ill. No. 04-CV-07312) (attached in the Appendix to this brief, Reply App. 24a–25a)

3. Merck argues that if appellate review in independent actions alleging fraud on the court were subject to ordinary summary judgment rules and *de novo* appellate review, no one would file Rule 60(b) motions for relief from judgment because it would be easy to circumvent the timeliness and other limitations imposed by Rule 60 by filing an independent action. (*See* Br. 11.) Of course, the plain language of Rule 60 envisions the independent action as an alternative to seeking relief under Rule 60 — that is the unmistakable import of Rule 60(d)'s savings clause, as we explain in the petition. (*See* Pet. 17–18.) If Merck were correct that an independent action is subject to precisely the same rules as a motion for relief under Rule 60, the savings clause would be a pointless exercise in surplusage.

In any event, what Merck brands "an absurd result" (Br. 11) fails to take account of the higher standard that confronts plaintiffs in an independent action. To ensure that independent actions do not circumvent the limitations on Rule 60 relief, the proper approach is not to ignore its savings clause, but to set the bar for relief in an independent action appropriately high. As this Court has explained: "Independent actions must, if Rule 60(b) is to be interpreted as a coherent whole, be reserved for those cases of 'injustices which, in certain instances, are deemed sufficiently gross to demand a departure' from rigid adherence to the

doctrine of res judicata." *United States v. Beggerly*, 524 U.S. 38, 46 (1998). Indeed, in *Herring*, the Third Circuit rejected the same argument that Merck now forwards, stating: "We are quite capable of taking full account of the narrow criteria for relief present in an independent action for fraud upon the court without altering the Federal Rules of Civil Procedure." 424 F.3d at 389.

4. Merck finally argues that under any standard of review, Apotex's allegations of fraud are wanting. (*See* Br. 12–13.) This assertion is belied not only by the record, but by the assessment of the Federal Circuit itself in a related case when it considered the very same evidence on which we now rely, but without the circumscribed standard of appellate review that it erroneously applied to this case.

In the original action between Apotex and Merck, as part of its motion seeking summary judgment on the ground that Apotex's patent was invalid because Merck had previously made the same invention and not "abandoned, suppressed, or concealed it" within the meaning of 35 U.S.C. § 102(g), Merck told the district court that it had not suppressed or concealed its process for making VASOTEC® tablets because it had published the ingredients as early as 1992 in its product monograph and in the 1988 edition of the *Dictionnaire Vidal*, and because Brian McLeod had described in open court the "details" of "Merck's process for making VASOTEC® tablets" during the Canadian litigation, which Merck characterized as an "unrestricted disclosure," adding that its "conduct in the late 1980s and early 1990s belies

any intention to keep its product secret." (Pet. App. 16a.) On just this basis, the district court ruled that Merck had not suppressed or concealed the invention because the ingredients for VASOTEC® were publicly available, and because Mr. McLeod's Canadian testimony and accompanying videotape "explained the process in detail," and Merck had "fully disclosed the ingredients and the process" in a way that was sufficient to show a person of ordinary skill in the art how to duplicate the process. (Pet. App. 15a.) On appeal, Merck again stated that it had not suppressed or concealed its invention because it had published the ingredients for the tablets; because it had made a detailed disclosure of Merck's entire process for making its tablets in the Canadian litigation; and because the VASOTEC® process could be reverse engineered simply by examining the tablets themselves and knowing the ingredients. (Pet. App. 16a.) Affirming the district court, the Federal Circuit concluded that Merck had "disclosed the ingredients used in manufacturing VASOTEC® tablets," and also "provided a step-by-step description of the process through the testimony given by Brian McLeod at the Canadian trial on March 28, 1994." *Apotex U.S.A., Inc. v. Merck & Co.*, 254 F.3d 1031, 1040 (Fed. Cir. 2001).

Years later, Warner-Lambert sued generic drug maker Teva Pharmaceuticals for infringement of its patented ACE inhibitor drug Accupril and Teva defended on the ground that the Accupril patent was obvious in view of Merck's pre-existing VASOTEC® tablet. *See Warner-Lambert v. Teva Pharmaceuticals USA, Inc.*, No. Civ.A. 99-922DRD, 2004 WL 1498162, *14 (D.N.J. June 29, 2004), *aff'd*

in part & rev'd in part, 418 F.3d 1326 (Fed. Cir. 2005). In that case, Merck's witness in the original Apotex case, Dr. Brenner, testified that Merck's top executives had decided to forego patent protection for VASOTEC® in favor of trade secret protection, knowing that the manufacturing process could **not** be reverse engineered through a physical examination of the VASOTEC® tablets or knowledge of the ingredients. (*See* Pet. App. 16a–17a.) Based on that testimony, the district court found that Merck had "made a deliberate decision to forego patent protection and instead to conceal from the public as a trade secret its process for stabilizing VASOTEC® using sodium bicarbonate;" that Merck was successful in "maintaining the process as a trade secret to the late 1980's or early 1990's;" and that Merck made "continuing efforts" during the 1994 Canadian litigation (on which Merck had convinced the district court and Federal Circuit to so heavily rely in the earlier Apotex case) "to withhold the role of sodium bicarbonate in that process." *Id.* at *20. On appeal, the Federal Circuit took the same view of the evidence, concluding that Merck "chose to retain the sodium bicarbonate stabilization process as a trade secret and to forego patent protection" because Merck "concluded that the competitors would not be able to figure out the process for making VASOTEC® from its ingredients alone – namely, the process used to stabilize enalapril against cyclization." *Warner-Lambert v. Teva Pharmaceuticals USA, Inc.*, 418 F.3d 1326, 1331 (Fed. Cir. 2005).

As the *Warner-Lambert* litigation demonstrates, when the Federal Circuit was not circumscribed by a deferential standard of

appellate review, it found the same testimony on which Apotex relies on this case demonstrated that Merck had made a conscious decision to conceal its manufacturing process for VASOTEC®. Applying the proper summary judgment standard in this case, a court could readily conclude that Merck's entire defense in the original litigation with Apotex was a fraudulent sham inconsistent with their strenuous and calculated efforts at concealment throughout the 1980s and 1990s — precisely the kind of conduct that would satisfy the concededly demanding standard for establishing fraud in an independent action.

To be sure, the justification for plenary review in this case does not depend on how the case would come out under the correct standard of appellate review. In our petition, we present for review only the question whether the court of appeals employed the correct standard of appellate review. Should the Court conclude that *de novo* review is proper, the Court would most likely remand this case to the court of appeals to apply the correct standard; the Court's general practice is not to decide in the first instance questions that have not yet been reached by the court of appeals. *See, e.g., Gonzalez v. Duenas-Alvarez*, 549 U.S. 183, —, 127 S. Ct. 815, 822–23 (2007); *Engine Manufacturers' Association v. South Coast Air Quality Management District*, 541 U.S. 246, 268–69 (2004); *West v. Gibson*, 527 U.S. 212, 223 (1999); *NCAA v. Smith*, 525 U.S. 459, 469–70 (1999). As we explain above, the conflict in the circuits over the proper standard for appellate review in an independent action merits plenary review; the question of how this case would turn out under the proper standard, in contrast, is of

little concern to anyone other than the parties. But to the extent that the strength of the evidence matters here, the Federal Circuit's own assessment in the *Warner-Lambert* litigation of the same evidence on which we rely here surely demonstrates that there is in this case a compelling showing of fraud.

CONCLUSION

For the preceding reasons, the petition for a writ of certiorari should be granted.

Respectfully Submitted,

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APPENDIX

FILED
Mar 24 2005
MICHAEL W. DOBBINS
CLERK, U.S. DISTRICT COURT

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

APOTEX CORP.,	)	
	)	No. 04C 7312
Plaintiff,	)	
	)	Judge Matthew F.
vs.	)	Kennelly
	)	
MERCK & CO., INC.,	)	
	)	PLAINTIFF DEMANDS
Defendant.	)	TRIAL BY JURY

FIRST AMENDED COMPLAINT

Apotex Corp. ("Apotex"), by its attorneys, for its First Amended Complaint against Merck & Co., Inc. ("Merck") alleges as follows:

1. This is an action by Apotex against Merck for relief from judgment entered by this Court in matter number 96 C 7375, for common law fraud, and for tortuous [sic, tortious] interference with prospective business advantage.

Parties, Jurisdiction and Venue

2. Apotex Corp. is a Delaware Corporation that maintains offices within this district.

3. Merck & Co., Inc., is a New Jersey company, whose principal offices are located at One Merck Drive, Whitehouse Station, New Jersey.

4. This action arises under the patent laws of the United States, Title 35, United States Code, and the Federal Rules of Civil Procedure Rule 60(b) as well as the laws of the State of Illinois. This Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§§§ 1331, 1332, 1338 and 1367.

5. Defendant is subject to personal jurisdiction in this judicial district.

6. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

Statement of Facts Common to All Counts

7. Apotex realleges paragraphs 1 through 6 above as if fully set forth herein.

8. On November 12, 1996, Apotex filed a Complaint against Merck alleging infringement of two United States Patents, USP 5,573,780 and USP 5,690,962 ("the Apotex patents"). Both patents were assigned to Apotex. That case became known as

Apotex USA, Inc. v. Merck & Co. Inc., Case No. 96 C7375 ("the 7375 action") in this district.

9. The Apotex patents disclosed the use of alkaline sodium compounds along with a certain amount of water, neither too much water nor too little water, to cause a chemical reaction with enalapril maleate which would lead to a stable dosage form of enalapril in a tablet or solid composition. The preferred embodiments used in the Apotex patents used either sodium carbonate or sodium bicarbonate.

10. Merck answered the Complaint in the 7375 action on January 2, 1997 and served a Counterclaim on Apotex. On June 8, 1998, Merck filed a motion and memorandum seeking summary judgment that the Apotex patent was invalid for derivation and inequitable conduct. On December 28, 1998, the motion for summary judgment was denied.

11. On March 12, 1999, Apotex filed a motion for summary judgment in the 7375 action alleging that Merck infringed the Apotex patents. On April 16, 1999, Merck responded to Apotex's motion and filed its own motion for summary judgment of noninfringement of the Apotex patents.

12. On November 17,1999, Merck filed a motion for summary judgment in the 7375 action that the Apotex patents were invalid under 35 U.S.C. Section 102(g) in that Merck was the first inventor of the patented process and had not suppressed, concealed or abandoned the invention of the patents. A copy of that motion is attached as Exhibit 1. In support of

the motion in the 7375 action, Merck also filed the Declaration of Gerald S. Brenner, Ph.D., a former Merck employee. A copy of the Brenner declaration is attached as Exhibit 2.

13. The Brenner declaration in the 7375 action stated that Brenner who had a Ph.D. in organic chemistry (paragraph 3) worked for Merck from 1961 through 1994 (paragraph 4). It further stated that he was involved with the development for the process of manufacturing enalapril maleate tablets (paragraph 4). Brenner further declared that Merck developed the process in the early 1980's, that the Merck Frosst's Product Monograph for Vasotec contained an accurate identification of the ingredients used in that process, that McLeod's testimony on March 28,1994 (in an earlier Canadian infringement trial between Apotex and Merck) provided an accurate summary explanation of the steps for making the product and that the process that Merck used was still being used to make its enalapril maleate tablets (paragraphs 5 and 6).

What Merck purposely and with the intent to defraud Apotex and the Court withheld from the Brenner declaration was that Merck decided to maintain the critical role of sodium bicarbonate in the process for making its enalapril maleate tablets as a trade secret; that, in fact, Merck maintained it as a trade secret at least to the early nineties; and, that, in fact, Merck knew that even knowing the ingredients in the tablets would not reveal the critical role of sodium bicarbonate in the process of stabilizing the enalapril maleate tablets, and without knowing that critical role, persons in the art would

not be informed as to Merck's process for making the stable enalapril maleate tablets.

14. On January 20, 2000, the Honorable Judge Matthew F. Kennelly, issued a Memorandum Opinion in the 7375 action ruling on Merck's motion for summary judgment of invalidity. In that decision, without knowing the facts that had been purposefully kept out of the Brenner declaration, the Court found, "Nor do the facts of this case suggest that Merck deliberately suppressed or concealed its invention." (Exhibit 3, page 14.) The Court found that the product monograph, Dictionnaire Vidal, and the disclosure at the Canadian infringement trial, "taken together" clearly and convincingly established that Merck did not intentionally suppress or conceal its invention." Based on this, the Court in a grave miscarriage of justice found that Merck had "neither abandoned, suppressed nor concealed that process," and entered judgment against Apotex invalidating the Apotex patents.

15. As part of the Court's ruling in the 7375 action, the Court found, based on Merck's arguments and material omissions, that the Apotex patents were invalid. As such, in a grave miscarriage of justice, Merck through its material omissions caused Apotex to lose the Apotex patents.

16. On February 3, 2000, without knowledge of the material omissions from the Brenner declaration and without the ability to know of the material omissions, Apotex filed a motion for reconsideration in the 7375 action.

17. On March 17, 2000, the Court denied the motion for reconsideration in the 7375 action by stating in part:

> "So the Court is left with the disclosure of the process through McLeod's testimony in the Canadian litigation in 1994, through the product monograph and through the Dictionnaire Vidal entry, plus the fact that Merck has been using the process commercially since 1983. The Court remains convinced that these disclosures clearly and convincingly prove Merck neither suppressed nor concealed its invention." (Exhibit 4.)

The Court did not and could not have known when it entered judgment against Apotex based on the material omissions from the Brenner declaration that Merck had kept the critical role of the sodium bicarbonate a trade secret and that:

> "It was the feeling within Merck having access to only that data, that was insufficient to teach somebody the role of sodium bicarbonate in the stabilization of the formulation." (Exhibit 5, Brenner May 3, 2004 trial testimony in the U.S.D.C. for the District of New Jersey case of *Warner Lambert Co. v. Teva Pharmaceuticals USA and Schwartz-Pharma. Inc.*, at pp. 164–65.)

18. On March 21, 2000, Apotex appealed the decision in the 7375 action.

19. During the briefing in the Federal Circuit, Merck never disclosed the material omissions from the Brenner declaration, but instead continued to argue to the Court of Appeals that the product monograph (which Merck also stated applied to the Dictionnaire Vidal), a public document, disclosed all the ingredients used in the formulation steps that Mr. McLeod set out on March 28, 1994.

20. Again, without knowing of the material omission by Merck, the Federal Circuit on June 8, 2001, caused a grave miscarriage of justice when it affirmed the District Court's opinion finding the Apotex patents invalid. (254 F.3d 1031 (Fed .Cir. 2001)). (Exhibit 6.) The Federal Circuit as a basis for its decision stated:

> "Merck made several disclosures following its period of suppression or concealment that made the invention publicly known, all of which took place before Apotex's entry into the field (here, Dr. Sherman's alleged conception in April of 1994). First, Merck disclosed the ingredients used in manufacturing VASOTEC® tablets in the 1988 edition of the Dictionnaire Vidal. It also widely distributed the product monograph in Canada from October 1992 through 1994, which similarly disclosed the ingredients it used in its manufacturing process. Merck also provided a step-by-step description of the process through the testimony given by Brian McLeod at the Canadian trial on March 28, 1994. . . . Merck's various disclosures, in conjunction

with Apotex's admissions, therefore clearly and convincingly prove that Merck made the knowledge of its invention available to the public, thereby satisfying its burden of rebutting Apotex's evidence of suppression or concealment." (254 F.3d 1031 at 1040, rehearing and rehearing en banc denied, cert denied.)

The Federal Circuit would not have found the patents invalid if it knew that Merck through its material omissions had kept from the Court and Apotex the fact that it had maintained the critical role of sodium bicarbonate a trade secret and omitted critical parts of the manufacturing process from the McLeod testimony.

21. On May 3, 5–6, 2004, in the United States District Court for the District of New Jersey, Gerald Brenner appeared as a witness in the case of *Warner-Lambert Company v. Teva Pharmaceuticals USA, and Schwarz-Pharma, Inc.* (the New Jersey action). Mr. Brenner's testimony is attached as Exhibit 5. Mr. Brenner, as noted by the trial court in the New Jersey action, had appeared as both Warner-Lambert's expert and Merck' 30(b)(6) representative on the topic of Merck's enalapril maleate tablets. (289 F. Supp. 2d 515, 535 (D.N.J. 2003)) Among the statements made by Mr. Brenner under oath concerning Merck's decision to maintain the critical role of sodium bicarbonate in its process for making Vasotec® as a trade secret were the following:

Q More specifically, Dr. Brenner, following the introduction of Vasotec in the

market place, did Merck decide to maintain the role of sodium bicarbonate in its process as a trade secret?

A Yes, it did. (Exhibit 5, page 156, lines 5–9.)

Q How long did Merck maintain its Vasotec process in the role of sodium bicarbonate in that process as a trade secret?

A I would say at least to the late eighties or early nineties. (Exhibit 5, page 156, lines 10–14.)

Q Was there any consensus at Merck at that time period regarding whether people in the field could discern Merck's process for the role of sodium bicarbonate in that process from this reference? [sic]

A The consensus within Merck was that knowing the ingredients themselves, the typical work in the field could not discern the process by which Merck made Enalapril tablets.

Q And do you know that fact from your discussions regarding whether to maintain that process as a trade secret?

A That was part of the discussion that went on relative to maintaining it as a

trade secret, and the consensus opinion was that knowing the composition alone would not have allowed the preparation tablets [sic]. (Exhibit 5, pages 157–8, lines 17–06.)

A The consensus opinion was that in just examining the tablets or analyzing the tablets, one would not be able to discern the process by which we prepared the tablets. (Exhibit 5, page 158, lines 17–20.)

Q And was there a consensus within Merck regarding whether people in the field could discern how to stabilize Vasotec or determine the role of sodium bicarbonate somehow in Vasotec from this package insert?

A The individuals involved in discussions within Merck were fairly confident that knowing the ingredients one would not be able to develop a stable product. (Exhibit 5, pages 161–2, lines 24–07.)

Q Can you explain why Merck felt that way? Why didn't Merck feel that the various threats [sic] of information you've identified now, Bolvadeer, the tablets, the package insert, in the Dictionnaire Vidal would not tell one in the field the role of sodium bicarbonate in the Vasotec process, and how to use that to stabilize Vasotec?

A Well, basically, you know, at that point in time when Merck decided to keep this as a trade secret, all of those individuals, mostly myself and two other individuals in the department were aware of perhaps around five years of work that had been done on Enalapril, the magnitude of the work, and the difficulty of stabilizing the tablet. And with that realization in hand, the three onus were essentially, were the primary movers in making that decision, felt that with the experience and the knowledge of the difficulty in developing the process, the ingredients, themselves, wouldn't be sufficient to develop the process without the kind of experimentation that we had to do over a long period of time. (Exhibit 5, page 165, lines 04–24.)

Q Dr. Brenner, in deciding to protect the Vasotec stabilization process in the role of sodium bicarbonate in that process, it's a trade secret [sic]. Merck expressly decided to forgo patent protection in its process. Correct?

A Yes, they did.

Q And that's a risky decision, isn't it?

A It's a risky decision. And those onus who were discussing that at the time weighed both options, and decided that

it would be in Merck's benefit to maintain it as a trade secret. (Exhibit 5, pages 166–167, lines 22–07.)

Q Now, can you identify the timeframe when you first became involved in the Enalapril project?

A It was in the early 1980s.

Q Now, did your involvement with the Enalapril formulation end at some point in time?

A It practically followed me until the day I retired. (Exhibit 5, page 590, lines 5–10.)

Q And now, Dr. Brenner, this chemical mechanism that you described as your working hypothesis to stable Enalapril, did you eventually come up with a manufacturing process to accomplish stabilization in accordance with that working hypothesis?

A Not directly.

A And there was a process in -- a process of time? Yes. It turned out to be much more complex. (Exhibit 5, pages 608–9, lines 19–01.)

Q Okay. Now, Dr. Brenner, once you discovered the existence of this reaction

by which you could stabilize Enalapril, you described that that wasn't the end, you have your problems; correct?

A Correct.

Q And why didn't discover the reaction, solve the problem of manufacturing a stable product of Vasotec?

A Because to really solve the problem one had to insure that the reaction took place, and we're really — we're fighting an uphill battle because we really don't have a lot of water in the wet granulation. And over time we continued to learn — as we are trying to develop this process, we were — it was a learning curve almost over a three-year period. The concept worked but to get it to work on the — on a repeatable way was very difficult. And we were learning all during maybe a two- or three-year period factors which impacted on how well that neutralization reaction worked. (Exhibit 5, page 610, lines 06–25.)

Q Now, why did you care about those other acid groups if you only want to get number 2 to lead?

A Because it can't go directly to number 2. If you're adding an agent like sodium

bicarbonate, the most acidic acid in the molecule is going to be converted first.

Q Okay.

A So we have to add enough sodium bicarbonate to fully satisfy this hydroxyl group before this one will start to be converted to the NA group.

Q And so you had to use enough sodium bicarbonate to get number 1 converted before you could get to the OH group that you're interested in?

A Right. And that's implied by this 2, 2 meaning that we had to add two parts of sodium bicarbonate for each one part of Enalapril maleate. One part of sodium bicarbonate wouldn't have been enough.

Q And the process of coming to this understanding, did that take sometime?

A Quite a bit. As I said, even before we could work on this working hypothesis we had to learn something about the order of conversion. So you couldn't have even started those experiments. Once we did those experiments, then we had an idea of the amount of sodium bicarbonate to add relative to Enalapril. This was an extremely time consuming process from the standpoint of getting first all of the background chemistry

under our belt and then going on to doing experiments to really prove the concept. So ultimately we did approve of concept experiments, and did show that neutralization of these two hydroxyl groups and converting them to this form here, which would be the ONA group on one of the maleic acids; and the converting Enalapril to Enalapril sodium, we did approve of concept study in which a wet granulation was used, two parts of sodium bicarbonate was used to one part of Enalapril, and that formulation gave us the first glimmer that we were approaching the solution to the problem. (Exhibit 5, pages 612–13, lines 07–20.)

Q And now on the screen is Plaintiffs demonstrative 20, can you explain what that is?

A These were some of the impacts that we learned over time would play an impact on whether the dosage form was stable or unstable. And I can read them off. The type of mixing equipment, the duration of mixing, the temperature of mixing, the holding time of the mixer before the wet granulation is dried, and the particle size of the sodium bicarbonate used in the process.

Q And now, was there a common element to all these factors that was found to be important with respect to stability?

A The common factor, and the success of the tablet that was manufactured, depended on the extent of the reaction. By that I mean if the reaction was complete, it was a hundred percent reaction. If it was incomplete, there could be anything from zero to ninety percent a reaction. The common threat in terms of correlating stability with these factors we learned over time was how far that reaction went, converting the OH group to the NA group. (Exhibit 5, page 617–18, lines 08–03.)

Q And now let's skip down, or if you want to talk about the temperature of mixing and duration of mixing together, how do those process variability affect the stability of Vasotec?

A Both of those factors, the longer the duration and the higher the temperature of mixing, the more complete the reaction was. And in terms of the total effort that was done in this program, I had indicated before, it was a very significant effort, the kind of experiments that we did that took so much time is like, we would make tablets mixings at maybe 15 minutes, 30 minutes, one hour, and two hours.

All of those tablets would be compressed and made into tablets and their stability study. Same thing with temperature mixing. We would run maybe mixed studies at room temperature, 40 degrees, 60 degrees, 80 degrees, and all of those experiments took extremely long periods of time to do and a lot of analytical support.

Q And now the various studies that you had to do to figure out the proper ranges for these five factors, aren't those just the type of normal experimentation one encounters when scaling up from the lab to the manufacturing plant?

A Definitely not. Typically in a normal product one would never look at the temperature of mixing. Most products are mixed at room temperature. This particular product is mixed at 80 degrees, which is almost 60 degrees centigrade over room temperature.

Q And is that unusual?

A Very unusual. I personally have no experience with any formulation being granulated and mixed at 80 degrees, so this is very A typical. [sic] (Exhibit 5, pages 619–20, lines 04–10.)

Q And would you give me Plaintiffs demonstrative 21, please. And now you

talked about the fact that extent of reaction is important. Is there anything in this document that supports that?

A This document is very supportive of that. I can read it off if you would likely much. [sic]

Q Okay.

A It's difference in the granulating step for Vasotec, from the typical wet granulation process is the chemical reactions evolved, the active ingredient, Vasotec, Enalapril maleate, needs to be neutralized by sodium bicarbonate, during granulating. Previous studies have shown that the drug stability strongly depends on the extent of reaction. (Exhibit 5, pages 621–22, lines 16–04.)

Q Okay. Are there any other reasons you want to explain to the Court why one could not reverse engineer the tablets to determine Merck's Vasotec process?

A I read off at least five factors that we determined were critical in the extent of the reaction. Quite a number of those factors could never be determined by reverse engineering.

Q And can you explain that a little bit, please.

A This is a unique formulation that it's wet granulated at 80 degrees. In my 25 years at Merck, I don't remember another granulation that's granulated at 80 degrees. You could not gain that information by looking at the tablet.

Q And that temperature was important to the stabilization process; is that correct?

A It enhanced the extent of reaction.

Q Okay. Now, Dr. Brenner, to your knowledge as of 1994, had Merck ever disclosed any element of its process or the role of sodium bicarbonate in that process publicly?

A Not that I'm aware of.

Q And as of 1994, when you left the company, were you aware of anyone in the industry that had figured out either the process or sodium bicarbonate's role in that process?

A Not that I'm aware of.

22. In reliance on the statement of facts by Brenner, which facts had been intentionally omitted by Merck from the Brenner declaration attached to Merck's motion for summary judgment in the 7375 action, the Court in the case of *Warner-Lambert Company v. Teva Pharmaceuticals USA, and*

Schwarz-Pharma, Inc. on June 29, 2004, made the following findings (Exhibit 7):

> "In a previous section of this opinion there is described the success which Merck achieved in maintaining the process as a trade secret to the late 1980's or early 1990's and the continuing efforts on Merck's part during the 1994 Canadian litigation to withhold the role of sodium bicarbonate in that process." (Exhibit 7 at page 16.)
>
> "Thus, before (and for a considerable time after) the conception of the invention disclosed in the '450 patent, Merck's Vasotec process had been deliberately suppressed and concealed." (Exhibit 7 at page 16.)

23. After June 29, 2004, Apotex obtained a copy of the publicly available decision in the case of *Warner-Lambert Company v. Teva Pharmaceuticals USA*, and *Schwarz-Pharma, Inc.* and learned for the first time that material omissions had been intentionally made from the Brenner declaration and false statements were made in the Brenner declaration. After obtaining the decision, Apotex obtained a copy of the transcript of Brenner's testimony from the case and learned the full extent of the material omissions that were not disclosed in the Brenner declaration.

24. Because of the material omissions that were not disclosed in the Brenner declaration and the false statement in the Brenner declaration, this Court found the Apotex patents that had been issued by the

United States Patent Office to be invalid. Not only was the ruling that the Apotex patents were invalid a grave miscarriage of justice, it was a fraud on the United States Patent system which had rightfully allowed the Apotex patents to issue.

Count I

Independent Action To Obtain Relief From Judgment

25. Apotex realleges paragraphs 1 through 24 above as if fully set forth herein.

26. By providing this Court with the Brenner declaration containing material omissions of fact that Merck suppressed, concealed and made false statements concerning Merck's use of sodium bicarbonate as a stabilizing agent up to and including the Canadian proceeding, Merck was able through its fraudulent acts to cause a grave miscarriage of justice to deprive Apotex of the Apotex patents.

27. Pursuant to Rule 60(b) of the Federal Rules of Civil Procedure, it is requested that this Court open the judgment in the 7375 action and set aside the judgment it entered in that case and find the Apotex patents not invalid.

Count II

Common Law Fraud Under Illinois Law

28. Apotex realleges paragraphs 1–27 above as if fully set forth herein.

29. The Brenner declaration filed with this Court in the 7375 action contained omissions of material fact and a false statement. Specifically, and without limitation, the Brenner declaration in the 7375 action purposely omitted the material facts that Merck had decided to maintain the critical role of sodium bicarbonate in its process for making enalapril tablets a trade secret; that Merck maintained it as a trade secret at least into the early 1990's; that the reaction involving the enalapril maleate and sodium bicarbonate had to and, that Merck knew that even if one had knowledge of the ingredients in the tablets, that knowledge would not reveal the critical role of sodium bicarbonate in the process of stabilizing the enalapril tablets.

30. Such omissions were material to the decisions of the District Court and the Federal Circuit Court of Appeals.

31. Brenner at the time he made the statements in the declaration presented in the 7375 action knew that Merck had made the decision to maintain the critical role of sodium bicarbonate in its process for making enalapril maleate tablets a trade secret; that Merck maintained it as a trade secret at least into the early 1990's; and, that Merck knew that even if one knew the ingredients in the tablets, that

knowledge would not reveal the critical role of sodium bicarbonate in the process of stabilizing the enalapril tablets.

32. Brenner was produced by Merck in the 7375 action as a 30 (b)(6) corporate designee. Thus, Merck itself was aware that the Brenner declaration contained omissions of material facts.

33. The Brenner declaration was provided to this Court with the intention that it would be used as a basis for finding that Merck had not suppressed or concealed the process at issue.

34. The Brenner declaration was provided to this Court with the intent that it be relied upon by the Court in finding the Apotex patents invalid.

35. The Court in the 7375 action relied upon both the statements made in the Brenner declaration and the statements omitted from that declaration in finding that Merck had not suppressed or concealed its invention and in finding the Apotex patents invalid.

36. Because of Merck's material omissions, Apotex has been damaged by having its patents held invalid and, therefore, losing substantial income that could have been derived from the licensing of the Apotex patents to Merck and others.

Count III

Tortious Interference with Prospective Economic Advantage under Illinois Law

37. Apotex realleges paragraphs 1–36 above as if fully set forth herein.

38. The Apotex patents were duly and properly issued U.S. patents prior to the Court's decision in the 7375 action.

39. Apotex had a reasonable expectation of being able choose between licensing the Apotex patents to pharmaceutical companies who wished to produce pharmaceutical products using the patented process or selling on an exclusive basis its enalapril tablets made by the Apotex patented method. Apotex had a reasonable expectation of being able to collect royalties from those licenses or profits from those sales.

40. Merck was aware that Apotex had such a reasonable expectation as Apotex was seeking to enforce its patents against Merck in the 7375 action.

41. By submitting the false and fraudulent Brenner declaration to the Court in the 7375 action, Merck purposefully and intentionally interfered with Apotex's ability and right to enter into such licenses or sell its product.

42. Merck's actions were purposely and intentionally done with the intent that this Court

rely on the misstatements and omissions in finding the Apotex patents invalid.

43. Apotex has been damaged by Merck's actions in that it has been unable to enter into any license agreements or sell any product on an exclusive basis and has thus foregone substantial income that could have been derived from licensing the Apotex patents or the exclusive sale of enalapril tablets made by the Apotex patented method.

WHEREFORE, Apotex prays for judgment and relief as follows:

a. That the judgment entered in *Merck v. Apotex*, Civil Action No. 96C7375, holding the Apotex patents invalid be vacated;

b. That Apotex receive an award of damages in an amount in excess of $75,000 to be determined by the jury for the injuries it has suffered because of the fraud committed by Merck;

c. That Apotex receive an award of damages in an amount in excess of $75,000 to be determined by the jury for the injuries it has suffered because of the tortuous [sic] interference with prospective economic advantage.

d. That Merck pay all of Apotex's costs in bringing this litigation.

e. That Apotex receive an award for punitive damages to be determined by the jury.

f. Grant all such other relief as the Court deems just and equitable.

Jury Demand

Apotex requests trial by jury for all matters that are triable by jury.

Dated: March 24, 2005

By: /s/ Robert B. Breisblatt

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